PRINCIPAL INVESTIGATOR AGREEMENT - EXAMPLE

FULL TITLE OF STUDY			
SHORT TITLE			
TRIAL ACRONYM			
PROTOCOL NUMBER			
EUDRACT NUMBER		**CLINICALTRIALS.GOV ID**	

This Agreement is made between:
[sponsor]
and *[PI name] of [Hospital] in [Country]*
as a collaborator for the [title] trial and supersedes all previous agreements, both written and oral.

A. PRINCIPAL INVESTIGATOR RESPONSIBILITIES

As the Local Principal Investigator you are responsible for the overall conduct of the trial in your hospital and agree to comply with the trial protocol. By signing this statement, you are confirming that you shall comply with all laws and statutes applicable to the performance of the clinical trial including, but not limited to, the Human Rights Act 1998, and with all relevant guidance relating to medicines and clinical trials from time to time in force including, but not limited to, the ICH GCP, the World Medical Association Declaration of Helsinki entitled *'Ethical Principles for Medical Research Involving Human Subjects'* (2008 version).

1. The Principal Investigator (PI) has reviewed the clinical protocol and agrees that it contains all the necessary information to conduct the study.
2. The PI agrees;
    a. Not to implement any deviation from or changes to the protocol without agreement of the Coordinating Centre and prior review and documented approval of the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard to the patient.
    b. To read the information in the Investigator's Brochure in advance of the trial starting at this hospital.
    c. To ensure that the trial is carried out to a high standard and in accordance with ICH Harmonised Tripartite Guideline for Good Clinical Practice (ICH GCP). In line with the GCP, audits of case report forms will be carried out.
    d. To ensure that source data are made available for verification when required by the Coordinating Centre or relevant regulatory authorities.
    e. That it is his/her responsibility to obtain all relevant ethics committee approvals for the conduct of this trial at his/her hospital and to have the written approvals copied to the Coordinating Centre before any patients can be randomised.
    f. To ensure that all doctors and nurses working with the trial at this hospital are properly trained in the procedures relating to the conduct of the trial, including Good Clinical Practice.
    g. To ensure that recruitment of a high number of patients into the trial is established and maintained. Recruitment targets will be agreed with the Coordinating Centre.

h. To ensure that any conditions of the ethics committee approval relating to obtaining informed consent are met.

i. To ensure patient confidentiality is maintained and to abide by the data protection laws in this country.

j. To ensure that patients' data forms are properly completed and returned to the Coordinating Centre in a timely manner.

k. To ensure that the data provided for the Coordinating Centre are accurate and valid.

l. To keep the individual username and password, allocated to the PI by the Coordinating Centre for the purposes of data entry, secure and confidential and not to share it with any other person.

m. To maintain adequate and accurate records of all trial drugs sent to this hospital whilst conducting the trial and to ensure that the drug accountability log and the randomisation log are accurately completed, and to report to the Coordinating Centre all damaged and lost treatment packs.

n. To ensure that the Investigator Study File is kept up to date and that signed original consent forms are kept in this file.

o. Within 24 hours, to report to the Coordinating Centre and the local ethics committee any serious adverse events as per protocol.

p. To report any safety issues to the local ethics committee as instructed by the Coordinating Centre.

q. That the sole responsibility for the release and communication of the results regarding the trial lies with the Coordinating Centre, and to keep all unpublished information transmitted between the PI and the Coordinating Centre strictly confidential and to not publish it or disclose it to a third party without the prior written consent of the Coordinating Centre.

r. To inform the Coordinating Centre immediately if the he/she leaves the employment of this hospital or is unable to continue in the role as PI for any reason.

s. To conduct the trial in accordance with the current protocol [version number & date] and any amendments, and all current legislations governing clinical trials in this country.

3. The Hospital agrees that this trial can be conducted at this institution and that in the event [PI name] can no longer fulfil the responsibilities of PI;

   a. To make all efforts to identify a replacement PI for this hospital.

   b. To ensure that Coordinating Centre is provided with all outstanding data.

B. FINANCIAL ARRANGEMENTS

Large trials involving many hospitals are important for future patients, but are practicable only if those collaborating in them do so without payment, except for recompense of any minor local costs that may arise. Agreement for reimbursement of local costs will be made in advance.

1. For the services detailed above, the Coordinating Centre will pay [PI/Hospital] costs associated with the trial related activities, provided they have been previously agreed with the Coordinating Centre.
2. [payment details]
3. [payment details]
4. The amounts itemised above will be paid to:
   Bank:
   Address of bank:
   SWIFT/IBAN/ABA code:
   Account holder:
   Account number:

C. TERMS

1. This Principal Investigator Agreement cannot be transferred to another person.
2. Any matters arising from this Agreement shall be agreed between [sponsor] and [PI name].
3. Any amendment or addition to this Agreement shall be agreed between [sponsor] and [PI name] in writing.

Signed

On behalf of sponsor [Name]	**Principal Investigator** [Name]	**On behalf of [hospital],** [Name of authorised hospital signatory]
Date:	Date:	Date