

PCT Research Governance Permission for an Industry-Sponsored Clinical Trial

Primary Care Trust.....

Investigator(s)

Sponsor.....

Study Title.....

NHS permission for R&D involving NHS patients

Department of Health guidance¹ says that when a trial is regulated under the Medicines for Human Use (Clinical Trials) Regulations 2004, NHS permission should normally be a formality if the sponsor:

- confirms who is authorised to act on behalf of the sponsor
- provides evidence of its Clinical Trial Authorisation (CTA) from the Medicines and Healthcare products Regulatory Agency (MHRA)
- provides evidence of a favourable opinion from a recognized research ethics committee
- provides details of indemnity and/or insurance
- ensures an appropriate process of independent expert review to demonstrate the study is worthwhile and of high scientific quality

and the PCT has no evidence of local factors that the ethics committee or the sponsor did not take into account which would make the study unsafe to conduct in this PCT or would harm service delivery.

Therefore [name of company] confirms that:

1. [name of company] is the sponsor of the trial and takes all of the sponsor's responsibilities under the Medicines for Human Use (Clinical Trials) Regulation 2004
2. [name of organisation] is the sponsor's legal representative for the trial sites in this PCT
3. the Chief Investigator has applied to [name of ethics committee] and will not start the study until the PCT confirms receipt of the ethics committee's opinion including Site-Specific Assessment for this study and the final versions of all documentation agreed by the ethics committee, along with details of any amendments that may be subsequently approved; a copy of the full documentation submitted to the ethics committee is provided
4. [name of sponsor] has applied to the MHRA for a CTA and will not start the study until the PCT confirms receipt of the CTA approval letter
5. copies of the ABPI/NHS form of indemnity (signed by the sponsor and GPs acting as Investigators at sites for which the PCT is accountable) and evidence of clinical trials insurance (if required by the ethics committee) will be provided to the PCT
6. scientific review has been completed according to [name of company] Standard Operating Procedures and including contributions from Investigators
7. all trial procedures are funded by [name of company], will not result in extra cost to the PCT and will not use PCT resources²
8. study medication will be provided by [name of company] until the time defined in the protocol and/or consent form

Signed on behalf of [name of company] by [name and title].....

Signature Date

NHS permission given for [name of PCT]

Signed on behalf of [name of PCT] by [name and title]

Signature Date

¹ *NHS permission for R&D involving NHS patients* (Department of Health, 2004).

² If available, the sponsor should also provide details of the cost of the treatment being tested and the likely number of patients involved, to aid PCT planning after completion of the trial.