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Statement on the responsibility for ongoing funding of experimental treatments for patients who have participated in commercially funded research

The Faculty of Public Health and the Association of Directors of Public Health are concerned that in some instances research sponsors may not be meeting their obligations to patients who participate in clinical research studies involving therapeutic treatments.

The *Medicines for Human Use (Clinical trials) Regulations 2004* state that in applying for an Ethics Committee opinion, the sponsor of the trial should supply details of "The plan for treatment or care of subjects once their participation in the trial has ended". This statement is based upon the World Medical Association Declaration of Helsinki. The statement does not necessarily imply that a commercial trial sponsor must continue funding of an experimental treatment beyond the end of the trial. However, it does imply that, if ongoing commercial funding has not been agreed then either: subjects must have consented to participation in the knowledge that their trial treatment will not be funded beyond the end of the trial, or local agreement should be reached that any ongoing treatment costs will be picked up by the NHS.

Agreement as to whether, and by whom, post-trial treatment of subjects will be funded should be reached before any research study is granted research ethics approval. It must not be assumed that NHS commissioners or provider trusts will be able and willing to pick up funding of experimental treatments at the end of commercially funded research studies without prior agreement.

Every funding decision has a public health dimension, because every such decision has an impact on the resources available for other services and treatments. Commissioners and provider trusts must not be forced into a position where they have to fund provision of treatments whose clinical and cost-effectiveness have not yet been established, at the expense of established services and treatments.

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