



MEDIA RELEASE

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NEW GUIDANCE FOR MICROBIAL CHALLENGE STUDIES OF HUMAN VOLUNTEERS

The Academy of Medical Sciences has published guidelines for those involved in conducting microbial challenge studies of human volunteers. Such studies involve the deliberate infection of volunteers with micro-organisms in order to understand disease and develop new vaccines.

The Academy's Working Group, chaired by Professor Richard Moxon of Oxford University concludes that 'it is imperative that the standards applied to microbial challenge studies of humans should be of equivalent stringency to those that pertain, for example, to research on drugs'.

The Group recommends the setting up of a National Expert Advisory Committee 'to identify mechanisms to safeguard the safety and welfare of human subjects involved in microbial challenge studies of humans'. Such a Committee, the Group suggests, should be established within an existing regulatory organisation. The Committee would have mandatory powers of inspection and, in certain circumstances, the power to stop research for safety reasons. Local safety monitors should also be introduced to look at studies on individuals on a case-by-case basis.

The guidelines emphasise the great importance of microbial challenge studies in developing effective vaccines to treat disease. The method of research was initiated more than two hundred years ago when Edward Jenner injected a vaccinated child with the smallpox virus. Current

research projects are working towards new vaccines to tackle threats to public health including emerging or novel diseases such as bird-flu, bio-terrorism and escalating resistance to antimicrobial treatments.

The guidance document also reviews the conduct of clinical trials, and reviews issues of ethics, transparency and accountability.

ENDS

Notes for Editors:

1. The independent Academy of Medical Sciences promotes advances in medical science and campaigns to ensure these are translated as quickly as possible into benefits for patients. The Academy's eight hundred Fellows are the United Kingdom's leading medical scientists from hospitals, academia, industry and the public service.
2. Media inquiries should be directed to Laurie Smith tel.: ++44 (0) 20 7969 5289 e-mail: laurie.smith@acmedsci.ac.uk
3. Copies of 'Microbial Challenge Studies of Human Volunteers – a guidance document' are available, free of charge, from The Academy of Medical Sciences , 10 Carlton House Terrace, London SW1Y 5AH, Telephone 020 7969 5288 or can be downloaded from the Academy's website: www.acmedsci.ac.uk