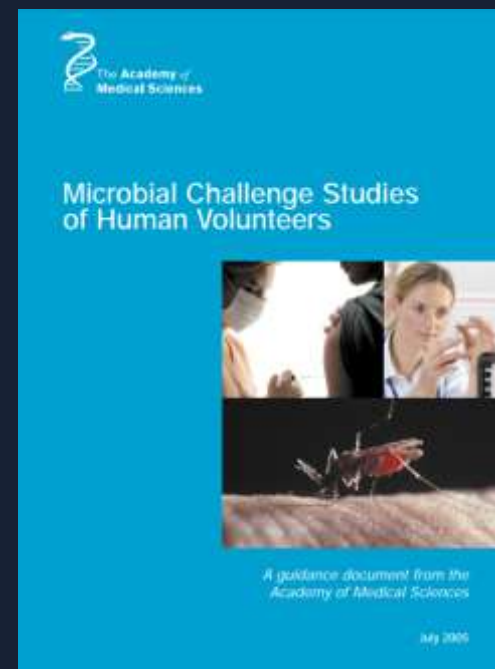


Human Challenge Studies: the 2005 Academy of Medical Sciences report

Professor Richard Moxon FRS FMedSci



AMS Human Challenge Studies (2005)

- Not adequately dealt with by European Clinical Trials Directives (Medicines for Human Use Regulations May 2004)
- Some unique features: deliberate induction of disease
- Anticipation of serious adverse events: need for accountability
- Need for specific guidance document: ethical, safety, legal and societal considerations

AMS Human Challenge Studies (2005)

- Need to emphasise value and provide historical perspective
- Do challenge studies differ fundamentally from other forms of clinical research on humans?
- Adequacy of current structures: institutional, national, international.