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## Summary

- The Academy supports the move towards seeking consent in a proportionate manner from patients to take part in real-world, large-scale simple and efficient research trials of existing treatments within the NHS.
- Our Fellows and other experts have provided a number of comments on the draft guidance that address:
  - Avoiding coercion during patient recruitment.
  - Specific guidance for obtaining consent during emergency care situations.
  - Verification of informed consent.
  - Clear feedback policy.
  - Appropriate training for healthcare professionals.
  - Clarification of health practitioners' duty of care.

## Introduction

The Academy of Medical Sciences promotes advances in medical science and campaigns to ensure that these are translated into healthcare benefits for society. Our elected Fellowship includes the UK's foremost experts drawn from a broad and diverse range of research areas, from basic research, through clinical application, to healthcare delivery.

### Support for proportionate regulation for simple and efficient trials: an overview

Low-risk pragmatic trials can take place now, but the procedures involved in relation to consent and information giving do not differentiate between high-risk studies of novel compounds and low-risk studies of commonly used treatments. The Academy supports the timely move towards simpler, more proportionate procedures when seeking consent for low risk-trials in the NHS. It is consistent with recommendations made in the Academy's 2011 report on health research governance, which is going to be followed up by a comprehensive review to assess impact. <sup>1</sup>

In consent Scenario One of the Health Research Authority's (HRA) draft guidance on seeking informed consent, invitations to join a study are made during routine consultations. <sup>2</sup> It will be important to avoid coercion in seeking consent and to give patients time and space to reflect before giving their written or oral consent.

Our Fellows and other experts have made a range of detailed comments.

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<sup>1</sup>The Academy of Medical Sciences (2011). *A new pathway for the regulation and governance of health research*.

<http://www.acmedsci.ac.uk/download.php?f=file&i=13646>

<sup>2</sup> The Health Research Authority (2014). *Draft guidance on seeking informed consent for simple and efficient trials in the NHS*.

<http://www.hra.nhs.uk/documents/2014/10/seeking-informed-consent-simple-efficient-trials-nhs-draft-guidance-comment.pdf>

## Detailed comments

### ***Emergency care studies***

The draft guidance does not address the fact that obtaining written consent may not be appropriate for some studies. It will be important to consider the situation in emergency care. An alternative option to obtaining written consent would be to obtain verbal consent prior to intervention, with witnessed assessment of understanding through three simple questions. Follow-up written consent could be then obtained when possible. This situation seems to be excluded by the HRA's proposed guidance.

### ***Verification of consent***

Obtaining verification of patient understanding when they are giving consent can be problematic. A more formal assessment of patient understanding through standardised questionnaires would be more appropriate than simply writing down that the patient has understood.

### ***Training***

It is important that good clinical practice and study specific training are considered for healthcare professionals treating patients in low-risk trials.

### ***Feedback policy***

In some studies extra procedures such as blood tests may be required. It will be essential to develop clear feedback policy in the event that any information of relevance to the health of the patient emerges.

### ***Duty of care***

The suggested principals listed in section 2.6 of the HRA draft guidance on seeking informed consent state that 'Healthcare Professionals have *the option* of using an intervention other than the one assigned'.<sup>3</sup> This point would benefit from clarification as, should the patient react poorly to a treatment, the clinician would have a clear duty of care rather than simply an 'option' to use another intervention. This is better described in the patient information sheet in section 2.7 of the HRA draft guidance on seeking informed consent.<sup>4</sup>

## Additional issues

The work of clinical laboratories may need to be considered if it is part of a research study. For example, consent may be required to use patient laboratory or clinical data in the evaluation of diagnostic tests already in use and to compare performance against patient outcome.

In consent Scenario Four of the Health Research Authority's (HRA) draft guidance on seeking informed consent, explicit verbal consent is sought for access to patient's medical records for follow-up in a cluster trial of pressure relieving mattresses.<sup>5</sup> No consent is sought for the research intervention (mattress) which represents standard care. It is unclear whether or when patients would be informed about the intervention. Furthermore, if access to records at another practice, or from other data controllers, is required it may be challenging to obtain verbal consent.

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<sup>3</sup> *Ibid.*, 1.

<sup>4</sup> *Ibid.*, 1.

<sup>5</sup> *Ibid.*, 1.

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