



Obstetric Anaesthetists' Association

(Registered Charity No 272190)

Promoting the highest standards of anaesthetic practice in the care of mother and baby

Guidelines for Obstetric Anaesthetic Research

The Obstetric Anaesthetists' Association recognises the difficulties faced by investigators, Research Ethics Committees and potential participants when considering obstetric anaesthetic research, and offers the following as guidance. It is hoped that these guidelines will both safeguard the interests of research participants and facilitate the research process.

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www.oaa-anaes.ac.uk**

Obstetric Anaesthetists' Association
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Guidelines for Obstetric Anaesthetic Research

1. General principles

- 1.1. Research in obstetric analgesia and anaesthesia is vital to ensure advances in knowledge, quality of care and safety of mothers (for the purposes of these guidelines, the term “mothers” includes pregnant women) and babies.
- 1.2. Investigators should always follow the principles set out in professional guidelines such as those issued by the Medical Research Council,¹ General Medical Council,² Royal College of Physicians³ and World Medical Association⁴, in particular:
 - Research Ethics Committee approval should always be obtained;
 - informed written consent should always be obtained BEFORE research begins;
 - the rights of the individual should be preserved;
 - respect for participants’ confidentiality should be maintained.
- 1.3. The welfare of the mother and the baby should always take priority over research aims.
- 1.4. The psychosocial and physical vulnerability of mothers (and their supporters/partners) should always be considered.
- 1.5. Multidisciplinary cooperation is essential. Investigators should always be sensitive to the views of midwives, obstetricians, neonatologists, general practitioners and other healthcare workers, who should be informed of the proposed anaesthetic research if appropriate. Investigators should also consider involving user groups or offering them information.⁵
- 1.6. The lead investigator has ultimate responsibility for ensuring the highest standards in the conduct of the study in all its aspects. Department of Health guidelines on research governance (including awareness within the Trust that the research is being planned) should always be followed.⁶

2. Information and consent

- 2.1. INFORMATION about studies should be given well enough in advance to enable potential participants to ask questions to help them reach an unhurried and informed decision. This will vary according to the woman, the unit and the nature of the study. Investigators should justify to the Research Ethics Committee their proposed timing for giving information to mothers and should use as many routes as possible to publicise their

studies (parentcraft meetings, posters, community midwives etc) with a named person to contact if more information is required. Supporters/partners should be included if possible.

- 2.2. CONSENT should be sought only when the conditions in 2.1. have been met.⁷ Although women may indicate consent close to the time they receive information, confirmation of informed consent should be sought as close to the time of randomisation/treatment (where appropriate) as possible, to ensure that women can put the proposed study into context. It may be appropriate to approach mothers after delivery to seek consent for postpartum studies. Investigators should justify their proposed timing for obtaining consent to the Research Ethics Committee.
- 2.3. In order to give consent women must be competent; i.e. they must be able to understand and digest the information supplied to them, to reach a balanced decision. This requirement may be difficult to satisfy during labour if the woman is distressed or has received drugs such as analgesics or sedatives. Women should not be recruited if there is any doubt about competence. Clinical judgement is required; consent should be sought only by staff who understand the study and its implications, and the relevant issues surrounding research ethics. The lead investigator must be satisfied that these conditions are met.
- 2.4. It is strongly suggested that the process of informed consent during labour be witnessed by a practitioner independent of the research, e.g. a midwife or obstetrician. This witness must be satisfied that the woman and her supporter/partner understand the study and its implications, and the right to decline without compromising her care.
- 2.5. Consideration should be taken of other studies that may be in progress within the maternity suite. It may be appropriate for women to consent to more than one study if each has no bearing on the other (e.g. a comparison of different forms of epidural analgesia for emergency Caesarean section and a study into the use of intrauterine pressure measurements), but this decision should rest with the lead investigator(s).
- 2.6. By necessity, many drugs commonly used in maternity care in the UK and worldwide are routinely given outside their product licence. If such a drug is the subject of the study, investigators should include an explanatory statement about its licensing status in the Patient Information Sheet and discuss this with the mothers. Where appropriate, they should also include advice relating to breast-feeding.

3. Record-keeping

- 3.1. The same standards of record-keeping, confidentiality and data management apply as for any other form of research.¹⁻⁴
- 3.2. If the study requires postpartum follow-up, the outcome of pregnancy should be noted to avoid inappropriate and distressing follow-up telephone calls or letters.
- 3.3. Women should be offered the chance to see the results of the study if they wish.

4. References

1. http://www.mrc.ac.uk/ethics_a.html
2. <http://www.gmc-uk.org>
3. Royal College of Physicians of London. Guidelines on the practice of ethics committees in medical research involving human subjects (3rd edition). London, 1996.
4. <http://www.wma.net/e/approvedhelsinki.html>
5. A charter for ethical research in maternity care. Association for Improvements in Maternity Services and National Childbirth Trust, London, 1997.
6. Department of Health. Research governance
7. Dorantes DM, Tait AR, Naughton NN. Informed consent for obstetric anesthesia research: factors that influence parturients' decisions to participate. *Anesthesia and Analgesia* 2000; 91: 369-373.

5. Acknowledgements

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6. Working Party

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