



Royal College of
Obstetricians &
Gynaecologists

Obtaining Valid Consent to Participate in Perinatal Research Where Consent is Time Critical

Clinical Governance Advice No. 6a

February 2016

Obtaining Valid Consent to Participate in Perinatal Research Where Consent is Time Critical

This is the second edition of this guideline, which was previously published in August 2010 under the same title. This guidance is intended to provide a good practice framework for researchers regarding i) the timing and detail of study information provision, and ii) the taking of consent for participation in research involving either mother or baby when, due to the nature of the study, valid consent is required while in labour or in the immediate postpartum period. Typically, this may be in the intrapartum period where eligibility for a study is established, for example, preterm birth is anticipated or planned, or in the neonatal period where the baby has or develops a specific condition. It should be read in conjunction with Royal College of Obstetricians and Gynaecologists (RCOG) Clinical Governance Advice No. 6 *Obtaining Valid Consent*.¹

This document does not cover issues relating to undertaking medical research in women who are deemed to lack the mental capacity to consent. Guidance on these issues is thoroughly covered by the Mental Capacity Act and the Medical Research Council.^{2,3}

1. General principles

Research should be undertaken ‘with women, not on women’ as outlined in *A Charter for Ethical Research in Maternity Care*.⁴ Investigators should always follow the *Research Governance Framework for Health and Social Care*⁵ (2005) and requirements from the Medicines and Healthcare products Regulatory Agency,⁶ together with guidelines for best research practice developed by professional bodies (e.g. General Medical Council,⁷ RCOG, Medical Research Council and World Health Organization). This should include the following:

- Service users should be involved in the development, delivery and publication of the trial and this should include the consent process and production and review of participant information sheets.
- Favourable ethical opinion and any additional regulatory approvals for any study should be obtained prior to undertaking any research activity. This should include trial-specific information and the consent process.
- Ideally, informed signed consent should be gained before any research begins. In acute situations, consideration should be given to oral consent being obtained prior to randomisation with written consent taken later.
- The rights of the individual should be respected and patient confidentiality maintained at all times.
- The welfare of the mother and baby should always take priority over any research aims.
- Special consideration should be given to the psychological and physical vulnerability of the mother and her partner.
- Providing that information is available antenatally, it is reasonable to take consent in labour as long as time is available for discussion and consideration.
- Consent should only be taken by someone with a full understanding of the trial who has undertaken appropriate training. Consideration should be given to using pictures, diagrams or videos to assist with information giving.

2. Provision of information

Informed consent from a person is an ongoing agreement to receive treatment, undergo procedures or participate in research after the risks, benefits and alternatives have been adequately explained to them. Therefore, researchers should provide information about planned research to the pregnant woman (and partner), allowing them sufficient time to consider, in the event of their suitability, whether they wish to participate in the planned research study.

Consideration should be given to the best way of providing information and a variety of sources can be used. These may include leaflets, posters, DVDs, and trial-specific internet sites that provide contact details of the research team in the event that the woman or her partner desires additional information. Ideally, information should be supported by a verbal discussion with someone with a full understanding of the trial.

Any potential benefits, suspected risks or adverse effects relating to the planned research should be presented in a way that the women is able to understand and has been approved by the relevant authorities. Also, it can be helpful to include both positive and negative framing⁸ (for example, a treatment will be successful for 97 out of 100 and unsuccessful for 3 out of 100). This may in some cases require the use of numerical aids (Table 1).

Table 1. Presenting information on risk

Term	Equivalent numerical ratio	Colloquial equivalent
Very common	1/1 to 1/10	A person in family
Common	1/10 to 1/100	A person in street
Uncommon	1/100 to 1/1000	A person in village
Rare	1/1000 to 1/10 000	A person in small town
Very rare	Less than 1/10 000	A person in large town

The above descriptors are based on RCOG Clinical Governance Advice No. 7 *Presenting Information on Risk*.⁹

3. Timing and content of information

Based on RCOG Clinical Governance Advice No. 7 *Presenting Information on Risk*⁹ (Table 1), researchers might want to consider the following timing plan:

- For conditions with a **suspected risk of occurrence of 1/1 to 1/10** (for example, research on partograms, cardiotocographs, operative vaginal deliveries, first- and second-degree perineal trauma or caesarean sections), a significant number of pregnant women are potentially eligible for such studies; therefore, the **full study information should be available to the woman during the antenatal period**. Where feasible, researchers might want to consider obtaining informed signed consent before labour and, if the event happens in labour, consent can be confirmed verbally. Usually randomisation would occur after consent has been confirmed and as near to allocation of the intervention as possible to minimise withdrawals.
- For conditions with a **suspected risk of occurrence of 1/10 to 1/100** (for example, research related to fetal blood sampling or obstetric anal sphincter injuries), providing full trial information to all pregnant women during the antenatal period for a condition or complication with a small incidence poses ethical issues and carries the risk of overburdening the woman. This could take the form of either excessive information (particularly if the maternity unit is participating in several studies) or unnecessarily provoking anxiety about events/complications that are relatively unlikely to occur. In this situation, one solution is for **summary information to be available antenatally and full trial information to then be provided to women when they become eligible**. This pathway provides initial outline information about the trial that is given to women during the antenatal period, with access to additional online information if required. Full trial information is then provided to women when they become eligible prior to seeking their informed consent. This pathway, originally developed by the University of Liverpool¹⁰ in collaboration with local consumer groups, ensures that eligible women have prior knowledge of the trial and are given the chance to

access additional information if required, without burdening the majority of women with unnecessary details of a trial that may not apply to them.

- For conditions with a **suspected risk of occurrence of less than 1/100** (for example, shoulder dystocia, unexplained preterm labour or uterine inversion), careful consideration should be given to avoiding unnecessary physical and psychological stress by providing detailed information about scenarios and situations that are rare. Therefore, it is appropriate for **summary information to be available antenatally** and the **full study information to be given if the event happens** or when the suspected risk of occurrence of the condition exceeds the background risk of 1/100 (as stated above). The majority of neonatal trials are likely to come under this grouping.

4. Obtaining informed consent

Care should be taken to gain and record informed consent at the most appropriate time; this will be determined by the nature of the study and the likelihood of the event that would make a woman eligible for recruitment. Opportunity should be given for the woman (and her partner) to discuss the study and have any questions answered before informed consent is obtained. Training of the staff involved in her care is important to enable this to happen.

In acute circumstances, it may not be appropriate to provide full study information at the time of a complication or there may not be time to fully discuss the study. For this situation, an oral consent pathway has been developed by the University of Nottingham in collaboration with consumer groups, including the National Childbirth Trust.¹¹ They suggest that the provision of antenatal information to women with brief oral consent at the time of the complication is appropriate. Full written consent is then obtained at a later stage. This is a pathway that researchers may wish to consider for individual studies.

References

1. Royal College of Obstetricians and Gynaecologists. *Obtaining Valid Consent*. Clinical Governance Advice No. 6. London: RCOG; 2015.
2. Legislation.gov.uk. Mental Capacity Act 2005 [http://www.legislation.gov.uk/ukpga/2005/9/contents]. Accessed 2015 Dec 22.
3. Medical Research Council. *MRC Ethics Guide 2007: Medical research involving adults who cannot consent*. London: MRC; 2007.
4. Association for Improvements in the Maternity Services, National Childbirth Trust. *A Charter for Ethical Research in Maternity Care*. AIMS; 1997 [http://www.aims.org.uk/Publications/CharterForEthicalResearch.pdf]. Accessed 2015 Dec 22.
5. Department of Health. *Research Governance Framework for Health and Social Care*. 2nd ed. London: DH; 2005.
6. Medicines and Healthcare products Regulatory Agency. Services and information [https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information]. Accessed 2015 Dec 22.
7. General Medical Council. *Good practice in research and Consent to research*. GMC; 2010 [http://www.gmc-uk.org/Good_practice_in_research_and_consent_to_research.pdf_58834843.pdf]. Accessed 2015 Dec 22.
8. National Institute for Health and Clinical Excellence. *Patient experience in adult NHS services: improving the experience of care for people using adult NHS services*. NICE clinical guideline 138. London: NICE; 2012.
9. Royal College of Obstetricians and Gynaecologists. *Presenting Information on Risk*. Clinical Governance Advice No. 7. London: RCOG; 2008.
10. Vernon G, Alfirevic Z, Weeks A. Issues of informed consent for intrapartum trials: a suggested consent pathway from the experience of the Release trial [ISRCTN13204258]. *Trials* 2006;7:13.
11. Pushpa-Rajah A, Bradshaw L, Dorling J, Gyte G, Mitchell EJ, Thornton J, et al.; Cord Pilot Trial Collaborative Group. Cord pilot trial - immediate versus deferred cord clamping for very preterm birth (before 32 weeks gestation): study protocol for a randomized controlled trial. *Trials* 2014;15:258.

This Clinical Governance Advice was produced on behalf of the Royal College of Obstetricians and Gynaecologists by: **Dr S Kenyon PhD, MA, RM, Birmingham¹; and Professor A Ewer MB ChB, MD, MRCP, FRCPCH, Birmingham²**

¹lead of the RCOG Intrapartum Clinical Study Group (CSG) ²member of both the Neonatal and Intrapartum CSGs.

and peer reviewed by:

Dr JM Patel, India; and the Royal College of Midwives.

The Women's Health Patient Safety Expert Group lead reviewer was: Mr TC Hillard FRCOG, Poole.

The chair of the Women's Health Patient Safety Expert Group was: Mr TC Hillard FRCOG, Poole.

All RCOG guidance developers are asked to declare any conflicts of interest. A statement summarising any conflicts of interest for this guideline is available from: <https://www.rcog.org.uk/en/guidelines-research-services/guidelines/cga6a/>.

This guidance has been developed as part of an initiative to encourage joint working between the RCOG CSGs led by Professor L Poston FRCOG (Chair of the RCOG Research Committee) and Dr M Turner (Neonatal CSG). The National Childbirth Trust has been consulted as part of the development process.

The final version is the responsibility of the Women's Health Patient Safety Expert Group of the RCOG.

The review process will commence in 2019, unless otherwise indicated.

DISCLAIMER

The Royal College of Obstetricians and Gynaecologists produces Clinical Governance Advice as an aid to good clinical practice. The ultimate implementation of a particular clinical procedure or treatment plan must be made by the doctor or other attendant after the valid consent of the patient in the light of clinical data and the diagnostic and treatment options available. The responsibility for clinical management rests with the practitioner and their employing authority and should satisfy local clinical governance probity.