

CCMO

DIRECTIVE ON THE GENERAL MEDICAL ETHICS ASSESSMENT AND REGISTRATION FORM (ABR form)

Directive of the Central Committee on Research Involving Human Subjects, the CCMO, under article 24 of the Medical Research Involving Human Subjects Act (WMO), on the use of the general medical ethics assessment and registration form by accredited medical research ethics committees.

Article 1

Accredited medical research ethics committees must use the ABR form shown in the appendix to this directive when assessing and registering medical research involving human subjects.

Article 2

1. Medical research ethics committees must check the completeness and accuracy of the information contained in the ABR form before issuing a judgement on a research protocol in accordance with the WMO. This check covers the data which can be verified on the basis of the contents of the research protocol.
2. If the medical research ethics committee is of the opinion that the ABR form has not been fully completed and/or contains inaccuracies, it shall not issue a judgement on the research protocol until it has drawn the issue to the attention of the party submitting the research protocol and has received a new, complete and accurate ABR form from that party.

Article 3

Medical research ethics committees shall send completed ABR forms on which they have issued a judgement in respect of the corresponding research protocol to the CCMO within three weeks of the date on which the judgement was issued.

Article 4

This directive enters into force as of 1 March 2002.

Article 5

This directive shall be published in the Government Gazette, with the exception of the appendix, which will be made available for inspection. A statement to the effect that the appendix is available for inspection will be published in the Government Gazette.

The Hague, The Netherlands, 13 December 2001

*On behalf of the Central Committee on Research involving Human Subjects,
Prof HKA Visser, chairman*

The general medical ethics assessment and registration form (ABR form) and the explanatory notes thereto are available for inspection at the secretariat of the CCMO, Parnassusplein 5, The Hague, The Netherlands. As from January 2002 the ABR form will also be available via the CCMO website (www.ccmo.nl).