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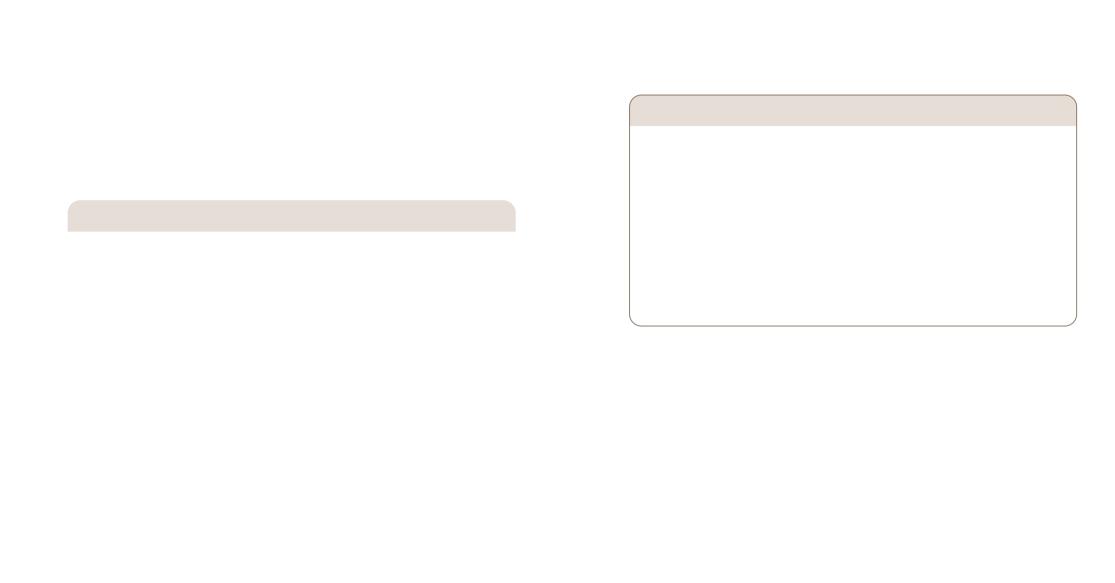
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MRC Ethics Guide: Medical research involving children

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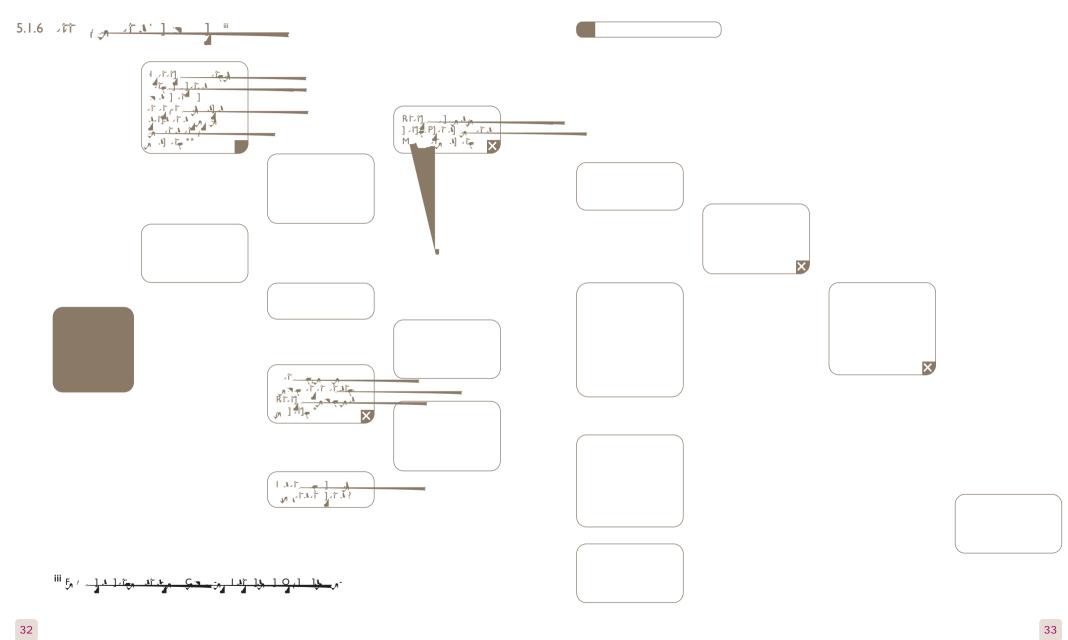
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Child

(b) either -

- (i) is evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent, or
- (ii) If the person is unable to sign or to mark a document so as to indicate his consent, is given orally in the presence of at least one witness and recorded in writing."

Confidentiality

The duty of persons to whom personal information has been given not to share the information with any unauthorised person. For more information about what this involves in practice, see 5.2.

Competence

The ability of a person, given the necessary information, to understand the nature and the consequences of the proposed procedure or treatment, and to use that information to make a valid choice in accordance with their own fundamental values. Please refer to 5.1.4.

Consent

The voluntary agreement of an adult or competent child, based on adequate knowledge and understanding of relevant information, to participate in research. For further information please refer to Section 5.

Family

A group of individuals who together form a social structure; a family may or may not include biological relatives.

Harm

That which adversely affects the interests or welfare of an individual. This may be physical harm, discomfort, anxiety, pain, and psychological

disturbance or social disadvantage (ostracism).

Investigational medicinal product

A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form."

Off-label

Term used to describe a medicine used for an indication, dose, or route of administration outside the terms of the product licence.

Parent/guardian

The term "parent/guardian" is used in these guidelines to describe those with legal responsibility for the child. The Children Act 1989, the Children (Scotland) Act 1995 and the Children (Northern Ireland) Order 1995 set out who has parental responsibility in their respective jurisdictions. The Adoption and Children Act 2002 s111(2) has recently extended the definition of those with legal responsibility for the child to include unmarried fathers who have entered into a legally binding Parental Responsibility Agreement."

The MRC is aware that some children will not be resident97600 10.02 40202 40.02 0

- 17. Be e Med c e C d e : ed e a ac aed a c ed c a d c .E., î] Ç, (EC)

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