



MRC Ethics Guide

2004

Moder of the

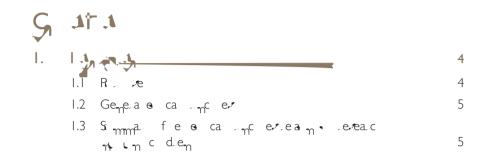
Med ca erea c $_{n+1}$  c $de_{n+1}$  m and for e benefit fa c $de_{n+1}$  eadre min ca min ea cale a can thran a min ce eo ea and i a ffe. Fin e mile, e ten fc aim efficie m bale mo d'folgen and tea mile been ea e.

Te Med ca Rereac  $C_{inc}$  (MRC) be ever a sereac  $m_{in}$  c  $d_{e_n}$ , i d be  $M_{in}$  ed,  $e_n$  c i a ed,  $a_n$  d c  $e_n$  d c ed  $m_{a_n}$  e  $a_n$   $m_{a_n}$  e. We  $a_n$   $e_n$   $e_n$   $e_n$   $e_n$  $e_n$  eac  $a_n$   $c_n$   $a_n$   $e_n$   $e_n$ 

We ec me a emin e and rae ibred i dance med ca ereac min c den rai a ea n c emix i der and i dance MRC ereacer. Te e i MRC i dance T cac d c a c c d (1991) arbeen e aced b ef n i da ed i de mer. Te i me e as ca, o ca and e a mer a erea cermed c mide en ca n i mider min c c den Q am arbeen ro i eme a mc er a can be a ed nm ria mi a e an cie e e mia Te i de merae mended be c more and ear eadabe, and mide a ma definition for e e e min red (ree See n7).

We refere to dance from TeR a Cee f Paeda cor and Cd Hear, 2 e De arment f Hear 3 and Borr Medica Arrica  $n^4$  to the ride ment. There are an arrival a cleft extref of many m

Tridec  $m e_m e_n$  i dance  $n \cdot e_n$  e ereacted cridiced b  $\cdot e MRC$ , a f criatabea  $\cdot e MRC$  ebse,  $mcaci \cdot A_n$  can ere MRC i dance a e  $\cdot ed_m$  ersear e are.



# 1.1 B、介

Tere i de merae der med be fire ereacer  $e a_m$  rarf MRCr ference much concernence ereacer  $a_mm$ , inder  $a_m$ cab  $a_m$  mic ereac. Te ar be ef ereacer, and de rand e ea ferr mar real en ma be much mereac, e crommerer, ereae much elem ereac, and e i b c.

Te i de meria e m accimiecent i b ca m b ead n and m and ferring b der, c a e efected i i. Te r i d be ead n c m n m RC i dance m d fferent ar ear f d accemierea c ad i (red m Sec m 8), e m c er f c a e ar e e and accement aed a c e e and e e a c e e e a c e e e a c e e e a c e e

### 1.2 Gî î ] î <u>]</u>

TeMRC  $r_{c}$  mm ed e ere carandad  $r_{n}$  med careta c. Te findamenta incerinde mm eta cin imposen rand nfime n ean em a ebeen eabla ed and efned nual i rapina and neme mai de ner<sup>5-12</sup>

- Telereal m a e en a ene a encentra frinde rand m a mabe a barr for m or  $e^{men}r$  m man ea  $a_{n}d$  e be n.
- Tele f s be an acce able balance for and benefit as c and
- Rereace  $r ca_n = ceed f$ , e are  $b a_n ed_i = n^{f} m^{ed} c n^{e} n^{f} f = a \cdot c a_n^{e}$ , a  $c a e_n^{e} e^{eac} (r eca rafe i a dra e_n^{e} r^{e} n^{e})$ .

## 

C denne i e recalmente e an e e recalmande e aber e a  $a_n$  adere be aber e e recalmente defende e neerrie e ma ne a e e ca ace de comente e ma ne a e e

Tef  $n = n^{-1}$  c didea MRC-finded ereac  $n \in n^{-4.5}$ 

Rereal c r i d n n ci de c d.e.n e.e. e.e.e.an n ed e cann. b
b a ned b .e.real c n ad .r (f i dance, ree 4.1)

- Te : re f. e.e.reac r b ann ed e.e.e.an. e ea., e ben ea cale need fc d.e.n
- Re-reace-rea<sub>n n n</sub> lec<sub>m</sub> een c den f e ale baned enf-med c n en bef e and.
- Ac dyrefra a cae c<sub>n n</sub>e nereacrida ar be ereced.
- •

Rereate  $m \cdot n \cdot e$  eat for demonstrate  $n \cdot e^{-x}$  a  $n \cdot f^{2}$ 

- N<sub>m</sub>ac d dde e m<sup>e</sup>n.
- O. mand ca rer fdreare.
- Mean f m n ea.
- Meant f.e.e.n., dan ..., arrenn and ean dreare.
- •

Wenac ce fae  $i \neq r$  when de c den r i d be  $r_{i}$  ed  $r_{i}$  efective  $i = r_{i} e^{r_{i}} a^{2} i \neq r_{m} e^{-e^{r_{m}} a^{2}} c$  i  $e^{r_{m}} a^{2} e^{r_{m}} e^{-e^{r_{m}} a^{2}} c$  i  $e^{r_{m}} a^{2} e^{-e^{r_{m}} a^{2}} e^{-e^{r_{m$ 

4.2 Tedan dan e i be een eater candnn eater cereac n eaded b man ar ne f and en a mreadn. Fre am e,



**Caef c** m'de a m f c me i encer ma bele i led den f r me r r en a  $a_m F = e a_m e$ , le reac m re i r en c dr de r a eren mad fe, le r m ma c da m r mac d, e ma be benefica, ma ar a e a mf effect m ca m c ma affect e c dr i n erand feed m f c ce.<sup>23</sup>

Line  $mf_n d_n$ , ar',  $ad \cdot r$ ,  $fe dence f a_m e_m e_r erd e_n$ ,  $e \cdot a ar a$ er,  $f \cdot n$ ,  $d_n ce \cdot a_n \cdot ea_m e_n$ ,  $e_n e_r err f, e c d$  $a \cdot c \cdot a_n r m r be <math>(\cdot bef \cdot e \cdot e_r e_n e_n r f)$ ,  $f \cdot e_r e_r e_r c \cdot T r m r b$  $a \cdot a_n n acc \cdot n b \cdot e_r e_r c \cdot e_m e_n r f \cdot e_r e_r decd_n n$  $m \cdot e_r f \cdot a_r a_n d m r der f n e \cdot ec n i err$ 

C di interne ea cinerne i des care n erame a ar e c d a c and Peare ree 5.1.4 f m e nf ma n i ro ca f a ea c d a c a e n erea c ar n ar a a c a e c men a rbeen b and, e e r n m e anmnma r and e erea c r n a and e c dr n e er.

Parca  $n n m e a_n n e e e a c a d a c a <math>n n m e a_n$  be a d a c a  $n n m e a_n n e a$ a d  $m e a_n n e a$ a

Et  $e_{i}$ ,  $e_{i}$ ,  $e_{n}$ ,  $e_{i}$ ,

4.3.2 M

ŕ

T e Na  $\pi^{a}$  Academ f. e Scencer der  $da_{n}$  ce  $\pi$   $\pi^{mnm^{2}}$   $der da_{n}$  ce  $\pi^{mnm^{2}}$   $der de e^{25}$ 

Monmon - nereac min c den

- Ir nair n fo den necera and e e e ten foi er n redbe e le reac? Waae eaer fe o den be na ded? A ean fe e en a ereac a mra e de enden?
- W en a c d a c an the the end f in multimetabe end f att call a tecfce ement f elereac?
- Wader elereacler e fo den and elfam er lradelence e elereacler cacher n' lfr, a ale elerre fn madelence?
- A e a · e · ced e ·  $n = e_n n' n = cera · a_n e · e · e e e a c · e · n?$  $Can e n e a · c e c · e · e · e d <math>n = n \cdot r n$  · ced e · a · e c d a · c a\_n · · · n de a · a · f · e · n · m · e a · m n · n?
- Have e reabla and der ann a creat , and er ad , a e da a ded a r fficen baref a creed n • creat n in c den?
- Des est d f \_\_\_\_ es fri \_\_\_\_ d\_ereac des \_\_\_?
- Waae e e e e e a ca $rr_{m}$  [ed e e e e a car red? A e da a a a a b e e  $r_{m}$  a e e b a b  $a_{m}d_{m}a_{m}$  i de feac  $rr_{m}a_{m}$  e e a e • e a e • e ca e e e f c d  $e_{m}$  b  $e_{m}$  ci ded?
- Have  $e_{n}$  er a ... ded da a  $n^{\circ}$  efference fade requention e ced era e require  $n^{2}F$  e  $a_{m}$  e, reda nf ereac ced era

S. . . .

- Ale enter a trand employ for elereaco eam rafed enfim each enced er are ment ected no encoded me en a trandadere roc mer Der elereaco eam a ean ae trande enternoam ficoden for eaex crided no est d?
- W ereac be estimed naron n a répender c'den fi ea er nrided n'erid? l'reron n'a raef e rca, c'nca, rc ca andem na need fi reae i r?
- For exercise  $a_{n}$  is the model of  $a_{n}$  and  $a_{n}$  and a
- If e = c even e = fa is a set of  $a = me e_{n}c$ , is e even  $c = me e_{n}c$ , is e even c = mdn. All  $a_{n} = me e_{n}c$ , is effect in  $d_{n} = me e_{n}c$ .
- Waae ex n i e pnd n f ea dr n f e e e a c n e barr from f n f e le e a c n f e le e a c n e barr from f n f d n r ab i e a m r bea-24.9(m7)TJ73 781.131 135.794 785.252 140.877 785.252 c475.207 785.252 484.411 781.131 484.411 776.048 c 595.138 841.945 mSQ | -0.138

20,•36.713

 $i_{n}$  de  $A_{n}$  d  $a \neq \ldots$  , red,  $A_{n}$  e.c.  $a_{n}$  d  $a_{n}$  d  $a_{n}$  f e.  $a e_{n}/i a d a_{n}$ ,  $a \neq e_{i}$  , ed b a.

E ca m  $a_n$ ,  $c_n$  c  $d_{e_n} a_{m}$  c  $a_n$  m  $be_n dec_n m a_n$  $e_n$   $e_n$ ,  $e_n$   $a_n$   $d_n$   $e_n$  c  $d_n$   $e_n$   $d_n$   $d_n$  d

Add ma - es mf - c den as c a m m c m ca - ar

Te Med c<sub>m</sub>erf - H<sub>mfm</sub> Ure (C<sub>m</sub> ca T.a.) Rei a m<sup>2</sup>2004 a e been a r<sub>m</sub>ce • e ca<sub>m</sub>e n f.ce n | Ma 2004 and ei a e ar n e UK.<sup>26</sup> Tere ei a m<sup>2</sup> an refi e an U<sub>m</sub> n D.es (e 2001/20/EC n UK a .<sup>31</sup> Te Rei a m<sup>2</sup> ffe add m<sup>2</sup> es n f a mm (a e minde, eae fl6 ear) r ben c m<sup>2</sup> de ed f a c n ca a. T radd m<sup>2</sup> es n c m<sup>2</sup> ra a me enm ec denaee esed, be ared, a cae n c n ca ar; a' a fan n e m<sup>2</sup> m<sup>2</sup> n a c e f esed be ared, a cae n c n ca ar; a' a fan n e m<sup>2</sup> m<sup>2</sup> n a c e f esed be ared, a cae n c n ca ar; a' a fan n e m<sup>2</sup> m<sup>2</sup> n a c e f esed be ared, a cae n c n ca ar; a' a fan n e m<sup>2</sup> m<sup>2</sup> n a c e f esed be ared, a cae n c n ca ar; a' a fan n e m<sup>2</sup> m<sup>2</sup> n a c e f m<sup>2</sup> es m<sup>2</sup>

24

### 5.1.4 A / ( 1.1 ) / 1.1 / 1.1 / 1.1 / 1.1 / 1.1

W  $e_n m_n^a$  ncearn  $ae, c_m e_n ce r c_m' de.ed_n d$ 

#### England, Wales and Northern Ireland

TeC den AG 1989 and TeC den AG (N = en Leand) O. de 1995 mae nf a en a n er es f e c d, n d d e e e e e  $med ca = e m en 3^{35,36}$  Care a r is a a er n a en a  $e^{r}$  mb e c c can ce ce a mon c d decriment f e c d n e e en a benefica e a men f i r f e ben e ber neer f e c d in er m

#### Scotland

TeC den (Sc. and) As 1995<sup>37</sup> ma et c. nf. cater e.ea in er na edinde 16 m c m een ie ea iad c men. Paena enab n aen ca i aen a er mb er ni de "afei ad n and m n ec de ea efae and de men, id n d es nand i dance ec d na mame a see eta a fec de de men and as n a ec de ea e eta aie." M e fete arin e in er n 16 ear d r r menc mae en decrimineer n m r As raed a ac d fl2 ear merid be er med be friffcen a eand mais finale. Te aena er mb i de i dance c n herin e in er n 18. Cate a r er a a aen cam, ie ie edecrimiter fac menc d; ee r ar b en cam, ie e edecrimiter fac menc d; ee

T e Ad  $\cdot$  Inca ac (Sc  $\cdot$  and) Ag 2000  $^{38ea70ca_{m}}$  a

5.1.4. تَتَرَبِ أَبَّرُنَ عَلَي <u>الْحَمَ</u>

Remeate en a direction and direction a direction a ceed.

5.1.5 H/ / / 1. / / 1 / / 1

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TeRCPCH der dance ber ree conten:<sup>2</sup>
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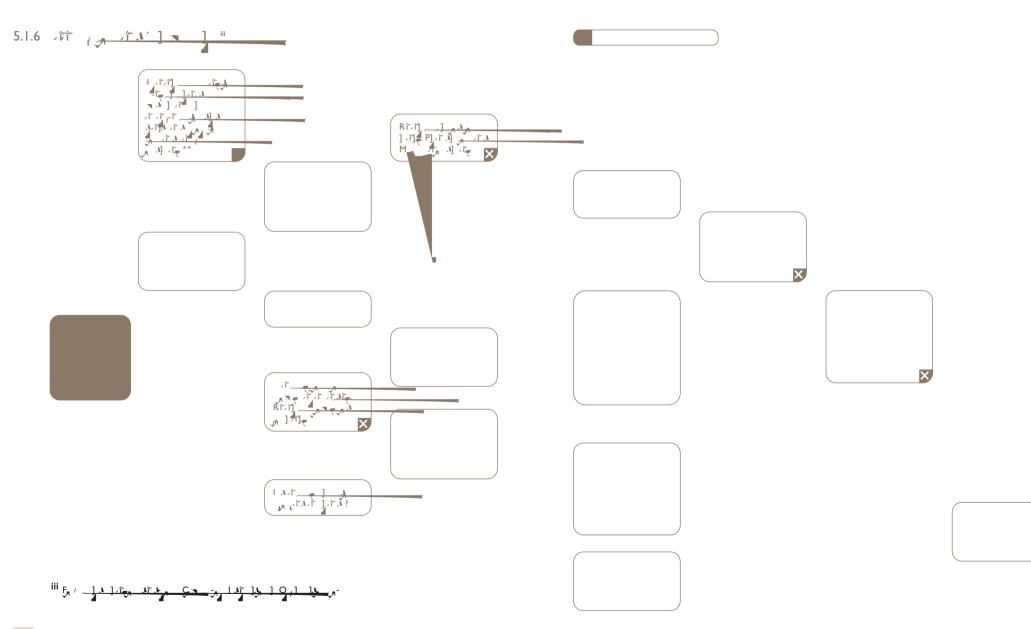
#### For consent to be freely given \_erea.c er m r:

- Offer farm er n franca nd cemen a i e enterride be ad.
- Ee. er e nfamer

•

- Gle emarmic mear rebe (afe darfama rid, fa a ribe). conde e a a a me e ec.

30



maile, e, m, er a m  $r_{\rm m}$  m ab r the rate as , adjce r id be r is form e. Rereated E. C.C. mm eet a appendence e... c.

A lereace reed, be a ale flee an da a lee ne ra nand, e r

e c' c  $mm^{n}$  ee.  $A_{n} e_{mm^{n}} = m^{n}$  for e a calce ab,  $mecerral <math>mecerral = m^{n}$  ee  $a_{n} = a_{n}$  for  $a_{n} = a_{n}$  for  $a_{n} = a_{n}$ . The area  $a_{n} = a_{n}$  and  $a_{n} = a_{n}$  and  $a_{n} = a_{n}$  and  $a_{n} = a_{n}$  for  $a_{n} = a_{n}$  for  $a_{n} = a_{n}$  and  $a_{n} = a_{n}$  and  $a_{n} = a_{n}$  and  $a_{n} = a_{n}$  for  $a_{n} = a_{n}$  and  $a_{n} = a_{n}$  for  $a_{n} = a_{n}$  and  $a_{n} = a_{n}$  for  $a_{n}$  and  $a_{n}$  and

W  $\star e C_{1n}c$  fills e = c rale  $a_{1n}c_{1n}e_{n}$ ,  $ar_{n}c_{n}r$  fabeen  $a_{1n}r$  red  $a_{1n}$  UK  $a_{1n}$  H  $e_{1}e_{1}$ ,  $e_{1}$  Med  $c_{1}e_{1}r$  for  $H_{1m}a_{1n}$  Ure ( $C_{1n}ca_{1}T_{1}a_{1}r$ ) Refar  $a_{1n}r^{2}2004$ ,  $c = a_{1n}r^{2}r$  e D refere  $2001/20/EC_{1n}$  UK  $a_{1n}e_{1}r$  e  $a_{1n}a_{1n}$  $e c r c_{1n}r^{2}ee_{1n}r^{2}$  and  $a_{1n}r^{2}r^{2}$  m  $m r^{2}r^{2}$  m  $r^{2}ece_{1}e^{2}$  and  $ce_{1n}r^{2}$  e  $a_{1n}r^{2}$  e  $a_{1n}r^{2}$ 

## 5.4 C \_\_\_\_\_\_\_\_/î \_\_\_\_/î \_\_\_\_\_/î \_\_\_\_\_

- 5.5 /<u>î-, .%].</u>
- 5.5.1 Rt 1 Peare efe. e MRC : dance H a a d b ca a a c  $1^{12}$

Fine i dance be med  $e_n \in H_m a_n T_m e_B$ ,  $a_n de i a e_n$ e ma  $n \in S_n$  and, bec mea.

## 5.5.2 $(a_n ce P a a dca ac.)^1$

### 5.5.3 Rîzî]

A  $a e_n/i a da_n e_n f_med c_m e_n \cdot necessa f_e_e_n e_me_n fbabes n$  $e-eac. W e_n a bab size is and a decs nabive <math>ea_me_n$  size i ed ic, e\_essee n  $a e_n \cdot s$  and edff f  $b a_{nn} \cdot s$  nf med c\_me\_n size need. T e RCPCH i des de a ed i dance e a n · see a c n i n bab est<sup>40</sup>

#### 

Under  $c_{mm}$  n  $a_{n}$ , ided a exected in face-reace of  $c_{mm}$  e arbeen  $ba_{m}edf$  e e is i.e. i.e.  $c_{n}$  i.e.  $ba_{mm}$  e ereac m in orden m ccar m feremet end i.e.  $ba_{mm}$  e  $c_{m}e_{m}$ . H ele, ele ration for m e a abi frequence der m ale e  $e_{m}a_{n}$  beneficed  $d_{m}$  i er m if m dib, idbe ad rabe ree e adice m end orden i row m in m

Reveac  $n \in n$  c den naneme encrita numa beneeded en ea men raaabe n ar a facereac  $a_{num}e$  is ca, for eleverac d erno a e e on a d celeror faces benefor ended a a c ano e Conc fill elec numendra a root d n be called of a e a m for not n more non ended and n for ended a r c nd nroot a condition ended and n for ended a r onde nroot a condition ended and n for ended a r onde nroot a condition ended a revenue of the ended a r

Remeace  $m \in m$  c den memerence si a mini i d be caued i me e e e e e a c f c m a a b e effecte e e e c caued i me e mini m m e me encosi a mi T e a e mini and c d mi s b e mi med ab i me e e e a c a s

## 7. G ]

Tedefn n' ded e e a ar e a er red n' e ab le r de ner.

#### Assent

Ac  $d_{f}$  affinate a seement as called Father best  $d_{n}$  be  $c_{m}$  is data seement.

#### Burden of disease

Te mas for earle n'ended a and mir co de for for a mand i a f fe. Mear er nci de () for bot b dense, e e a ence fa c nd me e an e for relevand e a edir b n for i a m i fferm form e c nd mand () e for anca b den i co mmeon e b a mar i e de da; for e am e, me mi for i b ce ender e mean relicer and mir carelicer.

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.<sup>\*\*</sup>

#### **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.<sup>4</sup>

The MRC is aware that some children will not be resident97600 10.02 40202 40.02 0 4

- 18. N]. ] A  $(A = \frac{1}{2} \frac{1}{2} \frac{1}{2} \frac{1}{2} \frac{1}{2} \frac{(HC 255 2002-2003)}{2} Sae, a, e cac: e a edce eUK. ] <math>(A = \frac{1}{2} \frac{1}{$
- 20. Μτ<u>i IIII Alt Act /Drlats-HrlatsHrlat</u> Μτ<u>i III Act</u> Οτ<u>i Act</u> Ηrlats Ηrlats Μτ<u>i III</u> Οτ<u>i C</u> στ.

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Mt.] <u>Rt.1]</u> <u>C.</u> 2004