

Human Tissue Authority new draft code: supporting child donors or supporting parents?

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ABSTRACT

The Human Tissue Authority has posted seven draft Codes of Practice to update its current guidance on human tissue legislation. Code G - *Donation of Allogeneic Bone Marrow and Peripheral Blood Stem Cells for Transplantation* - aims to improve the regulation of offences, referrals, and the interview process for children. The current version of Code G - Code of Practice 6 - has come under criticism for not properly taking into account the welfare of saviour siblings. Code G introduces minor changes to consent procedures but disappointingly, parents of saviour siblings can still enjoy significant discretion to consent to a potentially harmful trespass upon their child away from the objective provisions of the welfare test under section 1(3) of the Children Act 1989.

THE JOURNEY TO REFORM

The Human Tissue Authority (HTA) decided in September 2014 to produce a new set of streamlined Codes of Practice to guide professionals through the complex world of human tissue legislation. The donation and transplantation of organs/tissues is particularly complicated in law, requiring statutory consent for the use and storage of materials, but common law consent for the removal of materials.

A public consultation took place between 1st September and 30th October 2015 to offer members of the public and professionals an opportunity to relay their views on the revised Codes, which were consolidated from 1-9 to A-G. The consultation included workshops nationwide with 200 delegates and the accumulation of 97 written consultation responses.¹ In May 2016, newly drafted Codes A-G were uploaded onto the official Human Tissue Authority website (www.hta.gov.uk). Codes A-G will formally replace Codes of Practice 1-9 in April 2017 following Ministerial and Parliamentary approval, but have been posted a year in advance to allow professionals to familiarise themselves with the new guidelines.

BONE MARROW HARVESTS ON CHILDREN

Code G, *Donation of Allogeneic Bone Marrow and Peripheral Blood Stem Cells for Transplantation*, is of particular interest. It only received seven consultation responses despite the controversial issues surrounding the extraction of bone marrow from incompetent adult patients and children. Code G confirms that the use and storage of bone marrow from children is covered by the Human Tissue Act 2004, which states:

Section 1: Authorisation of activities for scheduled purposes

(1) The following activities shall be lawful if done with appropriate consent—

- (d) the storage for use for a purpose specified in Part 1 of Schedule 1 of any relevant material which has come from a human body;
- (f) the use for a purpose specified in Part 1 of Schedule 1 of any relevant material which has come from a human body;

Section 3: “Appropriate consent”: adults

¹ Codes of Practice & Standards Consultation Analysis, Human Tissue Authority, 2016, pages 10 and 11, <https://www.hta.gov.uk/launch-draft-hta-codes-practice-and-standards> (last accessed 7th July 2016).

(1) This section makes provision for the interpretation of “*appropriate consent*” in section 1 in relation to an activity involving the body, or material from the body, of a person who is an adult or has died an adult (“the person concerned”).

(2) Where the person concerned is alive, “*appropriate consent*” means his consent.

Section 2: “*Appropriate consent*”: children

(2) Subject to subsection (3), where the child concerned is alive, “*appropriate consent*” means his consent.

(3) Where -

(a) the child concerned is alive,

(b) neither a decision of his to consent to the activity, nor a decision of his not to consent to it, is in force, and

(c) either he is not competent to deal with the issue of consent in relation to the activity or, though he is competent to deal with that issue, he fails to do so,

“*appropriate consent*” means the consent of a person who has parental responsibility for him.

In practice, there are no controversial issues regarding the use and storage of bone marrow under the Human Tissue Act 2004, it is the *removal* of such material from children under the common law that is controversial, requiring an informed consent from the competent child (or someone acting on behalf of an incompetent child) to offset the criminal act that inevitably occurs during extraction (a malicious wound under section 20 of the Offences Against the Person Act 1861).² Parental consent in saviour sibling cases is highly subjective in light of the unique circumstances, leading to recent concern that the welfare of the donor child should be more rigorously scrutinised by the Human Tissue Authority (HTA) before the harvest is authorised.^{3 4 5 6 7 8 9 10} To add to the controversy, a tissue-matching embryo can also now be implanted into a mother following *R (Quintavalle) v Human Fertilisation and Embryology Authority (and Secretary of State for Health)* [2005] 2 A.C. 561 under Schedule 2 paragraph 1ZA(1)(d) of the Human Fertilisation and Embryology Act 1990 (as amended in 2008), meaning that newly born babies can be presented to the Human Tissue Authority as bone marrow donors for older siblings. Can these parents offer a balanced consent on behalf of the donor child that has objectively considered his or her welfare? In light of *Re Y (Mental patient: Bone Marrow Donation)* [1997] Fam. 110 - the only bone marrow donation case in the United Kingdom - it is clear that there must be a therapeutic benefit to the incompetent

² *JCC v Eisenhower* [1983] 3 All ER 230 and *R v Brown* [1994] 2 All ER 75.

³ Jecker, N.S. Conceiving A Child to Save A Child: Reproductive and Filial Ethics. *The Journal of Clinical Ethics* 1990; 1(2): 99.

⁴ Griner, R.W. Live Organ Donations Between Siblings and the Best Interest Standard: Time for Stricter Judicial Intervention. *Georgia State University Law Review* 1994; 10: 589.

⁵ Delany, L. Protecting Children from Forced Altruism: The Legal Approach. *British Medical Journal* 1996; 312: 240.2.

⁶ Crouch, R. and Elliott, C. Moral Agency and the Family: The Case of Living Related Organ Transplantation. *Cambridge Quarterly of Healthcare Ethics* 1999; 8: 275.

⁷ Pennings, G. Schots, R. and Liebaers, I. Ethical Considerations on Pre-Implantation Genetic Diagnosis for HLA Typing to Match a Future Child as a Donor of Haematopoietic Stem Cells to a Sibling. *Human Reproduction* 2002; 17(2); 534.

⁸ Glannon, A. and Ross, L.F. Do Genetic Relationships Create Moral Obligations in Organ Transplantation? *Cambridge Quarterly of Healthcare Ethics* 2002; 11: 153.

⁹ Cherkassky, L. The Human Tissue Authority and Saviour Siblings. *Journal of Bone Marrow Research* 2015; 3: 158-167.

¹⁰ Cherkassky, L. The Wrong Harvest: The Law on Saviour Siblings. *The International Journal of Law, Policy and Family* 2015; 1: 1-20.

donor to offset the trespass to their person. This benefit may be physical or psychological, but related case law confirms that a patient must have *awareness* of a benefit for a medical procedure to be in his or her best interests: *Re D (A Minor) (Wardship: Sterilisation)* [1976] Fam. 185; *Re Eve* (1986) 31 D.L.R. (4th) 1, Supreme Court of Canada; *Re B (A Minor) (Wardship: Sterilisation)* [1988] A.C. 199; *Re F (Mental Patient: Sterilisation)* [1990] 2 A.C. 1; *Curran v Bosze* (1990) 566 N.E.2d 1319; *Airedale N.H.S. Trust v Bland* [1993] A.C. 789; *Re A (Male Sterilisation)* [2000] 1 F.L.R. 549; and *An NHS Trust v MB* [2006] EWHC 507. The question is, does the newly drafted Code G contain fresh safeguards to protect young donors from highly subjective parental consent and the physical or psychological harm that could follow as a result of being harvested without their knowledge or understanding?

CONTROVERSIES: CODE OF PRACTICE 6

The current problematic regulations in Code of Practice 6 regarding the removal of bone marrow from children are as follows (these provisions have also been transferred into the newly drafted Code G albeit under different paragraph numbers):

Paragraph 60: Accredited Assessor's should only be interviewing donors who have been judged by the clinical team to lack capacity or competence to consent to removal of transplantable material. The HTA advises that Accredited Assessors (AA's) should interview younger child donors along with the person providing the consent on their behalf.

Paragraph 60 states that only incompetent children should be interviewed, but what about competent teenagers who consent, refuse, or are indifferent? They are just as prone to coercion, if not more, because they understand more about the potential consequences. Paragraph 60 also states that the younger donor should be interviewed alongside the parent giving consent. This would probably not glean any reliable information from the donor child, as the presence of the parent may silence the child.

Paragraph 65: In cases where donors are unable to give consent themselves, i.e. children who are not competent to consent... the decision about consent will be made by a person acting on their behalf.

Paragraph 72: Even small children can be helped to understand some aspects of the procedure and its associated risks. This understanding can be assisted by involving a play therapist, psychologist or specialist nurse in the communication process so that the child can gain a better understanding of what the donation would involve.

Paragraph 72 is of particular concern as it stipulates that children can be used as bone marrow donors at such a young age that they require play therapists, psychologists or specialist nurses simply to communicate. This is a concern because according to the common law, the best interests of the patient "must be proven".¹¹ It would be very, very difficult to prove a tangible psychological benefit in a donor this young, and a relationship must already be established between the young siblings for any benefit to be gleaned from a bone marrow donation between them.¹²

¹¹ *Re A (Male Sterilisation)* [2000] 1 F.L.R. 549, per Butler-Sloss L.J. at page 555.

¹² *Curran v Bosze* (1990) 566 N.E.2d 1319, per Calvo J at pages 1343-4.

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3 **Paragraph 81:** A person who has parental responsibility can consent to the storage
4 and use of bone marrow for transplantation on the child's behalf if there is no decision
5 by the child either to, or not to, consent, and:

- 6 1. the child is not competent to deal with the issue of consent to donation for
7 transplantation (i.e. non-Gillick competent); or
- 8 2. even though the child is competent to do so (i.e. Gillick competent), they
9 have not made a decision about consent to donation for transplantation.

10 In these cases, a person with parental responsibility can consent to storage and use of
11 bone marrow for transplantation on behalf of the child, if the donation is assessed as
12 being in the child's overall best interests, taking into account not only the medical but
13 also emotional, psychological and social aspects of the donation, as well as the risks.
14 The consent of only one person with parental responsibility is necessary.
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17 Paragraph 81 states that the consent of only one parent is necessary. This is rather unfair to
18 the child in the event that the second parent is absent and may have provided a more
19 objective, balanced view. However, should the second parent be available and disagree with
20 the procedure, the opinion of the High Court will be sought, triggering an application of the
21 welfare test under s.1(3) of the Children Act 1989 (confirmed at paragraphs 37 and 85 of
22 Code of Practice 6). A test case has not happened yet, but social aspects are not to be merged
23 with best medical interests,¹³ there is to be no balancing act between two siblings when
24 ascertaining welfare,¹⁴ the benefit must be tangible in the present and not speculative in the
25 future,¹⁵ and the outcome of death is not to be offset against life.¹⁶ It is also worth noting that
26 for incompetent adult donors, validation from the High Court is mandatory before the Human
27 Tissue Authority can consider the case (at paragraphs 36, 54 and 91). It is not clear why
28 children do not get the same protection.
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32 **Paragraph 83:** It is good practice that the practitioners involved assess the donor
33 child's best interests by talking to the child and the person who has parental
34 responsibility for them.
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36 Paragraph 83 encourages practitioners to talk to parents to ascertain the best interests of the
37 child, but not only would the parent be highly subjective, an investigation into the welfare of
38 the child should require strict objectivity to ensure his or her paramountcy under section 1
39 of the Children Act 1989. There is also no point in talking to the donor child if they are too
40 young to understand, which allows the parent to become a 'mouthpiece' and offer a
41 substituted judgment on the child's behalf.¹⁷ Speculative future benefits do not count,¹⁸ and
42 the child must remain paramount in both a national¹⁹ and international context.²⁰ It is
43 questionable whether a parent could adhere to all of the above.
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46 **Paragraph 85:** Where there is any dispute between people with parental
47 responsibility or any doubt as to the child's best interests, the matter should be
48 referred to the court for approval. In such instances, the HTA would then only
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51 ¹³ *Re A (Male Sterilisation)* [2000] 1 F.L.R. 549.

52 ¹⁴ *Court of Appeal* [1993] 1 F.L.R. 883 and *Birmingham City Council v H (A Minor)* [1994] 2 A.C. 212.

53 ¹⁵ *Curran v Bosze* (1990) 566 N.E.2d 1319.

54 ¹⁶ *McKay v Essex Area Health Authority* [1982] Q.B. 1166.

55 ¹⁷ Cherkassky, L. Children and the Doctrine of Substituted Judgment. *Medical Law International*, 2015; 1: 1-23.

56 ¹⁸ *Curran v Bosze* (1990) 566 N.E.2d 1319, per Calvo J at pages 1319, 1326 and 1336.

57 ¹⁹ Section 1(3) of the Children Act 1989.

58 ²⁰ *Re C (A Child) (HIV Test)* [2000] Fam. 48.

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3 consider the case for approval if the court was of the view that the donation was in the
4 best interests of the donor child.
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6 Paragraph 85 is the most important provision in Code of Practice 6, referring to court
7 approval. This provision is not as supportive as it first seems. There must be a disagreement
8 between the relevant parties before the inherent jurisdiction of the court is invoked, meaning
9 that a highly subjective parental consent is the primary mechanism for moving the very
10 young donor child into the harvesting process. Frustratingly, paragraph 85 goes on to say that
11 in the event of court involvement, only when an approval is in place from the court would the
12 Human Tissue Authority proceed with the case. Why cannot this high standard of welfare be
13 applied to every donor child?
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16 **Paragraph 89:** Children will also often experience feelings of responsibility or duty
17 when faced with the prospect of being a donor. In some circumstances children may
18 experience feelings of guilt or fear that love may be withdrawn if they do not proceed
19 with donation, and these feelings could influence the child's decision to donate. In
20 trying to determine whether a child has been coerced into donating, it is important for
21 the Accredited Assessor to discuss any feelings of pressure or duty the child holds and
22 explore their origins.
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25 Paragraph 89 acknowledges feelings of 'responsibility, duty, guilt and fear' in child donors
26 and encourages the discussion of such feelings, but when the parent giving consent is
27 encouraged to be present during interviews (as stated in paragraphs 60 and 83), it is not clear
28 how evidence of coercion could possibly be fairly and objectively gleaned from the donor
29 child.
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32 It is clear that the current version of Code of Practice 6 contains numerous legal and moral
33 difficulties. The welfare test under s.1(3) of the Children Act 1989 is not referred to
34 anywhere, which is particularly startling considering the non-therapeutic nature of the
35 procedure upon the child.
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37 **CHANGES AND PROBLEMS**

38 Numerous changes have been added to Code G, but they remain problematic for the very
39 young donor child. For example:
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42 **Paragraph 42:** Gillick competence means that a child is considered legally
43 competent to make their own decisions on medical treatment matters when that child
44 has sufficient understanding and intelligence to fully understand what is
45 proposed...the child can give or refuse consent.

46 **Paragraph 43:** It is the duty of the clinician responsible for the care of the donor to
47 ensure a competence test is undertaken before a case is referred to the HTA.

48 **Paragraph 44:** Consent from a person with parental responsibility on behalf of a
49 legally competent child will not be treated by the HTA as lawful consent...the HTA
50 considers that parents cannot make medical treatment decisions on behalf of a child
51 who can make his or her own medical treatment decisions.
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54 The new competence test under paragraph 43 is helpful as it allows teenage donors to make a
55 competent and autonomous decision about donation under *Gillick* that can, according to the
56 Human Tissue Authority, override their parents (paragraph 47 adds that the Court of
57 Protection can be consulted to confirm the competence of the donor child, adding some
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3 welcome objectivity into the consent process for removal). However, this provision is not
4 helpful to younger donors, and *Gillick* competent children are often overruled: *Re P (A*
5 *Minor)* [1986] 1 FLR 272; *Re E (unreported)* 21st September 1990; *Re R (A Minor)*
6 *(Wardship: Consent to Treatment)* [1992] Fam. 11; *Re E (A Minor) (Wardship: Medical*
7 *Treatment)* [1992] 2 FCR 219; *Re R (A Minor) (Wardship: Consent to Treatment)* [1992]
8 Fam. 11; *Re W (A Minor) (Medical Treatment: Court's Jurisdiction)* [1993] Fam. 64; *Re E (A*
9 *Minor) (Wardship: Medical Treatment)* [1994] 5 Med. L.R. 73; and *Re P (Minor)* [2003]
10 EWHC 2327.
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13 **Paragraph 97:** In all cases the AA must undertake, or attempt to undertake, an
14 interview with the donor. The only exception is where the donor unarguably lacks
15 capacity, for example attempting an interview with a baby or a pre-verbal child. In
16 these cases the AA must clearly report to the HTA the reasons for not seeing the
17 child.
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20 The Human Tissue Authority acknowledges very young donors for the first time under
21 paragraph 97, perhaps as a result of *R (Quintavalle) v Human Fertilisation and Embryology*
22 *Authority (and Secretary of State for Health)* [2005] 2 A.C. 561 and schedule 2 paragraph
23 1ZA(1)(d) of the Human Fertilisation and Embryology Act 1990 (as amended in 2008).
24 However, it adds no extra protection to very young donors from being used for harvest
25 without a welfare test or proof of a therapeutic benefit. There is no real protection afforded by
26 this paragraph - it is an empty provision.
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29 **Paragraph 99:** On occasion, a donor may express a wish not to go ahead with the
30 procedure. A parent or best interest's decision maker can override the donor's wish
31 not to proceed with the proposed donation...the decision maker must clearly
32 demonstrate that he or she has weighed up all the factors and reached the conclusion
33 that the donation is in the donor's overall best interests. The HTA must be satisfied
34 that the person consenting on the donor's behalf has properly taken these views into
35 account before reaching their decision.
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38 It is a new option for parents to explicitly override a child refusal, and it causes considerable
39 discomfort. Firstly, even though the courts overrule competent children, the parents are doing
40 it for their own ends without an objective welfare test. Secondly, it is not clear whether the
41 refusal is from an older calm child or a young distressed child, which could make a difference
42 to the distress caused to the child. Thirdly, overriding a refusal directly conflicts with
43 paragraphs 42, 44, 45, 46 and 73 of Code G, which clearly state that a decision about
44 donation from a competent child will be respected. Fourthly, a psychological benefit is
45 clearly not present if the donor child expressly disagrees, meaning that his or her welfare is
46 not met. Fifthly, the Human Tissue Authority must be "satisfied" against what criteria? What
47 about the paramountcy of the welfare of the donor child? Why does the decision to harvest
48 not include the Court of Protection if the donor is competent enough to form his or her own
49 rejection? This is actually quite shocking.
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52 **Paragraph 103:** The AA report will need to address whether the person consenting
53 on the donor's behalf has been placed under any duress or coercion to consent to the
54 procedure...in reaching a decision about whether [pressure] constitutes duress or
55 coercion the HTA would need to make a judgment on whether the will of the person
56 providing consent has been overborne such that they can no longer make an
57 independent decision.
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4 Paragraph 103 places a new emphasis on duress or coercion to the consent giver. This has
5 replaced paragraph 89 in Code of Practice 6 (stated above), which sought to explore feelings
6 of “responsibility, duty, guilt and fear” within the child donor. Why has the emphasis shifted
7 from child duress to parental duress? Is it an acknowledgment that parents may be influenced
8 by family or other external factors when consenting? If so, what happens now to any feelings
9 of responsibility, duty, guilt and fear felt by the child donor? Is the child donor even asked
10 about these issues any longer? This regulatory ‘swap’ is a great loss for the welfare of the
11 child.
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14 **Paragraph 105:** There may be occasions when the person consenting on the donor’s
15 behalf may have a conflict of interest in making their decision, for instance where
16 they are also, or are closely related to, the intended recipient.

17 **Paragraph 106:** Provided the HTA is satisfied that the parent or other decision maker
18 has made a decision which is focussed on the right questions and has acted properly in
19 a way that focuses on the best interests of the child making the donation, a conflict of
20 interest will not prevent the parent’s consent being given on behalf of the donor child
21 and being legally valid consent.
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24 This is a new and direct reference to saviour siblings and a response to the recent criticism.
25 The Human Tissue Authority may be trying to quash concerns that parents of donor children
26 cannot offer an objective consent, but a discretionary checklist of “right questions” does not
27 solve this problem. What are the right questions? The phrase “conflict of interest” should
28 automatically trigger an application to the Court of Protection to ensure objectivity and
29 transparency. The fact that the decision to harvest a very young saviour sibling could still be
30 validated behind closed doors using discretionary criteria without any mention of the
31 statutory/common law of welfare is very worrying.
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34 **CONCLUSIONS/REMAINING QUERIES**

35 It appears, from newly drafted Code G, that the Human Tissue Authority has listened to
36 recent concern that the welfare of the donor child (especially saviour siblings) is not fairly or
37 objectively considered before the harvest is authorised and has openly acknowledged that
38 difficult familial cases containing conflicts of interest do occur, but it has not offered any
39 tangible safeguards or precautions against non-therapeutic procedures and highly subjective
40 consent from parents. It is baffling that the Court of Protection are not called upon in every
41 child donor case to ensure the welfare of the child in light of such unique circumstances. We
42 await the first test case with interest.
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