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Implementation: To be determined by each Service

Change Notification UK National Blood Services No. 7 - 2015

Communication Difficulties

Applies to the Tissue Donor Selection Guidelines for Live Donors, Tissue Donor Selection Guidelines for Deceased Donors, Cord Blood Donor Selection Guidelines, and Bone Marrow and PBSC Donor Selection Guidelines

Please modify the entries as follows:

i) Living Tissue Donor Selection Guidelines

Obligatory

1. All donors must:

- a) Fully understand the donation process.
- b) Give their informed consent to the process and to the testing of their blood for diseases that may affect its suitability for use.

2. Third party interpreters:

If they are to be present at any part of the selection procedure where there is an exchange of confidential information between the donor and the qualified health professional, they must:

- a) Understand the importance of providing an accurate and truthful translation of the information provided, to enable the tissue/cell establishment to comply with regulatory requirements
- b) Not be personally known to the donor
- c) Fully understand their duty of confidentiality and the confidential nature of any information obtained from the donor

See if Relevant

Disabled Donor

Additional Information

The Services are aware of their duties under Race Relations and Disability Discrimination Legislation and will, whenever and wherever reasonable, try to provide facilities for individuals whose first language is

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not English, or who have other difficulties in communicating. **Every donor must:**

- a) Complete a health and medical history questionnaire and undergo a personal interview performed by a health professional.
- b) Provide informed consent to proceed with the donation process. This consent must be given in the presence of the qualified health professional responsible for obtaining the health history. The qualified health professional may be physically present or in communication with the donor by telephone

A qualified health professional may assist a donor in the completion of the health and medical history questionnaire and in understanding the consent statement and any other information provided by the Blood/Tissue Service. To facilitate comprehension it is permissible to use alternative formats (e.g. a language other than English, audio, computer, Braille) for the donor information leaflets, the health and medical history questionnaire and consent statements. The donor must be able to clearly demonstrate they have understood this material. At present there is no standardized way of assessing comprehension so this will be a personal judgement made by the qualified health professional.

Use of third party interpreters.

It is permissible for any third party to act as an enabler by helping to reassure the donor and to assist in establishing effective communication between the donor and the qualified health professional. The third party **must not** however be present during any exchange of confidential information, unless they are **not** personally known to the donor and understand the need to accurately and truthfully communicate all the information, including personal and confidential information, provided by the person giving consent. Confidential parts of the process include the evaluation of the health and medical history questionnaire, the medical interview and the obtaining of valid consent.

Rationale.

There is concern that the use of third parties during any exchange of confidential information between the donor and the qualified health professional may compromise the confidentiality of the donor and the safety of the blood supply. Interpreters are often part of a close community, or a family member, and this may inhibit or embarrass the potential donor in any confidential exchange of information. This may result in the non-disclosure of sensitive information that could affect the individual's eligibility to donate. If a third party is not fully aware of the need to accurately and truthfully communicate all the information, including personal and confidential information, provided by the person giving consent, this may make the interpretation of information incomplete and potentially put both the donor and any donated tissue at risk. There is also a requirement to communicate the results of any

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testing performed by the Blood/Tissue Services that may be of relevance to the donor's health in a way that protects their confidentiality. The continuing availability of an independent interpreter, to maintain donor confidentiality, should be taken into account when deciding if an individual donor may be accepted.

Reason for Change

1. To clarify that interpreters and translators do not need to understand all the regulatory requirements of the Human Tissue Act, but are aware of the importance of providing a truthful and accurate translation to enable the tissue/cell establishment to comply with regulatory requirements
2. To clarify that interpreters and translators have a duty of confidentiality
3. To clarify that consent for donation need not be signed by the donor, it can be taken by telephone

ii) Deceased Tissue Donor Selection Guidelines

Obligatory

1. All persons giving consent must:

- a) Fully understand the donation process.
- b) Give their informed consent to the process and to the testing of the donor's blood for diseases that may affect the suitability of their tissues for use.

2. Third party interpreters:

If they are to be present at any part of the selection procedure where there is an exchange of confidential information between the persons giving consent and the qualified health professional, they must:

- a) Understand the importance of providing an accurate and truthful translation of the information provided, to enable the tissue/cell establishment to comply with regulatory requirements
- b) Not be personally known to the donor or to the persons giving consent.
- c) Fully understand their duty of confidentiality and the confidential nature of any information obtained from the donor

Additional Information

The Services are aware of their duties under Race Relations and Disability Discrimination Legislation and will, whenever and wherever reasonable, try to provide facilities for individuals whose first language is not English, or who have other difficulties in communicating.

Any persons giving consent must:

- a) Undergo a personal interview performed by a health professional.

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b) Provide informed consent to proceed with the donation process. This consent must be given in the presence of the qualified health professional responsible for obtaining the health history. The qualified health professional may be physically present or in communication with the person giving consent by telephone.

A qualified health professional may assist in the completion of the health and medical history questionnaire and in understanding the consent statement and any other information provided by the Blood/Tissue Service. To facilitate comprehension it is permissible to use alternative formats (e.g. a language other than English, audio, computer, Braille) for the information leaflets, the health and medical history questionnaire and consent statements. The persons giving consent must be able to clearly demonstrate they have understood this material. At present there is no standardized way of assessing comprehension so this will be a personal judgement made by the qualified health professional.

Use of third party interpreters.

It is permissible for any third party to act as an enabler by helping to reassure the persons giving consent and to assist in establishing effective communication between them and the qualified health professional. The third party **must not** however be present during any exchange of confidential information, unless they are **not** personally known to the persons giving consent or to the donor and understand the need to accurately and truthfully communicate all the information, including personal and confidential information, provided by the person giving consent. Confidential parts of the process include the evaluation of the health and medical history questionnaire, the medical interview and the obtaining of valid consent.

Rationale.

There is concern that the use of third parties during any exchange of confidential information between the persons giving consent and the qualified health professional may compromise the confidentiality of the process and the safety of any tissue donated. Interpreters are often part of a close community, or a family member, and this may inhibit or embarrass the persons giving consent in any confidential exchange of information. This may result in the non-disclosure of sensitive information that could affect the eligibility of the deceased person to donate. If a third party is not fully aware of the need to accurately and truthfully communicate all the information, including personal and confidential information, provided by the person giving consent, this may make the interpretation of information incomplete and potentially put any tissue donated at risk. There is also a requirement to communicate the results of any testing performed by the Blood Services that may be of relevance to the donor's partner/family's health in a way that protects their confidentiality. The continuing availability of an independent interpreter, to maintain confidentiality, should be taken into account when deciding if an individual donor may be accepted.

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Reason for Change

1. To clarify that interpreters and translators do not need to understand all the regulatory requirements of the Human Tissue Act, but are aware of the importance of providing a truthful and accurate translation to enable the tissue/cell establishment to comply with regulatory requirements
2. To clarify that interpreters and translators have a duty of confidentiality
3. To clarify that consent for donation need not be signed by the person giving consent, it can be taken by telephone

iii) Cord Blood Donor Selection Guidelines

Obligatory

1. All mothers must:

- a) Fully understand the donation process.
- b) Give their informed consent to the process and to the testing of their blood for diseases that may affect the suitability of their baby's stem cells/tissues for use.

2. Third party interpreters:

If they are to be present at any part of the selection procedure where there is an exchange of confidential information between the mother and the qualified health professional, they must:

- a) Understand the importance of providing an accurate and truthful translation of the information provided, to enable the tissue/cell establishment to comply with regulatory requirements
- b) Not be personally known to the mother.
- c) Fully understand their duty of confidentiality and the confidential nature of any information obtained from the donor

See if Relevant

Disabled Donor

Additional Information

The Services are aware of their duties under Race Relations and Disability Discrimination Legislation and will, whenever and wherever reasonable, try to provide facilities for individuals whose first language is not English, or who have other difficulties in communicating. **Every mother must:**

- a) Be provided with accurate educational materials, which are written in terms which can be understood by members of the general public.
- b) Complete a health and medical history questionnaire and undergo a personal interview performed by a health professional.

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c) Provide written informed consent to proceed with the donation process which must be countersigned by the qualified health professional responsible for obtaining the health history.

A qualified health professional may assist a mother in the completion of the health and medical history questionnaire and in understanding the consent statement and any other information provided by the Blood/Tissue Service. To facilitate comprehension it is permissible to use alternative formats (e.g. a language other than English, audio, computer, Braille) for the information leaflets, the health and medical history questionnaire and consent statements. The mother must be able to clearly demonstrate they have understood this material. At present there is no standardized way of assessing comprehension so this will be a personal judgement made by the health professional.

Use of third party interpreters.

It is permissible for any third party to act as an enabler by helping to reassure the mother and to assist in establishing effective communication between the mother and the health professional. The third party **must not** however be present during any exchange of confidential information, unless they are **not** personally known to the mother and understand the need to accurately and truthfully communicate all the information, including personal and confidential information, provided by the person giving consent. Confidential parts of the process include the evaluation of the health and medical history questionnaire, the medical interview and the obtaining of valid consent. Any third party, with the permission of the mother, may accompany the mother through other parts of the donation process that do not include the exchange of confidential information.

Rationale.

There is concern that the use of third parties during any exchange of confidential information between the mother and the health professional may compromise the confidentiality of the mother and the safety of any donated material. Interpreters are often part of a close community, or a family member, and this may inhibit or embarrass the mother in any confidential exchange of information. This may result in the non-disclosure of sensitive information that could affect the individual's eligibility to donate. If a third party is not fully aware of the need to accurately and truthfully communicate all the information, including personal and confidential information, provided by the person giving consent, this may make the interpretation of information incomplete and potentially put both the mother and the donated material at risk. There is also a requirement to communicate the results of any testing performed by the Blood/Tissue Services that may be of relevance to the mother or her baby's health in a way that protects their confidentiality. The continuing availability of an independent interpreter, to maintain confidentiality, should be taken into account when deciding if an individual mother may be accepted.

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Reason for Change

1. To clarify that interpreters and translators do not need to understand all the regulatory requirements of the Human Tissue Act, but are aware of the importance of providing a truthful and accurate translation to enable the tissue/cell establishment to comply with regulatory requirements
2. To clarify that interpreters and translators have a duty of confidentiality

iv) Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines

Obligatory

1. All donors must:

- a) Fully understand the donation process.
- b) Give their informed consent to the process and to the testing of their blood for diseases that may affect its suitability for use.

2. Third party interpreters:

If they are to be present at any part of the selection procedure where there is an exchange of confidential information between the donor and the qualified health professional, they must:

- a) Understand the importance of providing an accurate and truthful translation of the information provided, to enable the tissue/cell establishment to comply with regulatory requirements
- b) Not be personally known to the donor.
- c) Fully understand their duty of confidentiality and the confidential nature of any information obtained from the donor

See if Relevant

Disabled Donor

Additional Information

The Services are aware of their duties under Race Relations and Disability Discrimination Legislation and will, whenever and wherever reasonable, try to provide facilities for individuals whose first language is not English, or who have other difficulties in communicating. Potential donors with such difficulties are advised to seek advice from their local Blood Service before offering to donate stem cells to see if their needs can be met. **Every donor must:**

- a) Be provided with accurate educational materials, which are written in terms which can be understood by members of the general public.
- b) Complete a health and medical history questionnaire and undergo a personal interview performed by a health professional.
- c) Provide written informed consent to proceed with the donation process which must be countersigned by the qualified health professional responsible for obtaining the health history.

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A qualified health professional may assist a donor in the completion of the health and medical history questionnaire and in understanding the consent statement and any other information provided by the Blood Service. To facilitate comprehension it is permissible to use alternative formats (e.g. a language other than English, audio, computer, Braille) for the donor information leaflets, the health and medical history questionnaire and consent statements. The donor must be able to clearly demonstrate they have understood this material. At present there is no standardized way of assessing comprehension so this will be a personal judgement made by the health professional.

Use of third party interpreters.

It is permissible for any third party to act as an enabler by helping to reassure the donor and to assist in establishing effective communication between the donor and the qualified health professional. The third party **must not** however be present during any exchange of confidential information, unless they are **not** personally known to the donor and understand the need to accurately and truthfully communicate all the information, including personal and confidential information, provided by the person giving consent. Confidential parts of the process include the evaluation of the health and medical history questionnaire, the medical interview and the obtaining of valid consent. Any third party, with the permission of the donor, may accompany the donor through other parts of the donation process that do not include the exchange of confidential information.

Rationale.

There is concern that the use of third parties during any exchange of confidential information between the donor and the qualified health professional may compromise the confidentiality of the donor and the safety of any donated material. Interpreters are often part of a close community, or a family member, and this may inhibit or embarrass the potential donor in any confidential exchange of information. This may result in the non-disclosure of sensitive information that could affect the individual's eligibility to donate. If a third party is not fully aware of the need to accurately and truthfully communicate all the information, including personal and confidential information, provided by the person giving consent, this may make the interpretation of information incomplete and potentially put both the donor and the blood supply at risk. There is also a requirement to communicate the results of any testing performed by the Blood Services that may be of relevance to the donor's health in a way that protects their confidentiality. The continuing availability of an independent interpreter, to maintain donor confidentiality, should be taken into account when deciding if an individual donor may be accepted.

To comply with both the HTA and Health and Safety Regulations no donor can be accepted if it unnecessarily puts their own safety or the safety of others at risk.

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Reason for Change

1. To clarify that interpreters and translators do not need to understand all the regulatory requirements of the Human Tissue Act, but are aware of the importance of providing a truthful and accurate translation to enable the tissue/cell establishment to comply with regulatory requirements
2. To clarify that interpreters and translators have a duty of confidentiality

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