FAIR III: can the policy recommendations from FAIR be safely and effectively applied to tissue and cell donors across the UK?

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1. Executive summary and recommendations

In 2019, the FAIR I steering group took an evidence-based approach to reviewing whether a more individualised risk-based blood donor selection policy could be introduced in the UK. The work focussed on men who have sex with men (MSM) and recommended that changes to the then population-based donor selection criteria should be made to introduce a gender-neutral risk-based approach at an individual level. At the time, the donor selection guidelines deferred MSM from blood donation for 3-months from last sex with a man. SaBTO accepted the FAIR recommendations and following government approval these were implemented in summer 2021. Under the new

system donors are asked additional questions about sexually transmitted infections, 'chemsex', and new and/or multiple sexual partners within the last 3-months. Those donors with recent new and/or multiple partners are asked an additional question about anal sex. Subsequently a question about sex with someone who had had sex in an area where HIV is endemic was also removed as other FAIR questions replaced the need for this specific question. The FAIR recommendations were based on evidence from epidemiology, behaviour and psychosocial data and identified specific, effective questions which would identify potentially higher risk sexual behaviours whilst being acceptable to donors and blood service staff.

The need for changes to tissue and cell donor policies were reviewed following previous major changes to blood donor selection related to sexual behaviours. Following the FAIR change, the possibility of applying this approach to other donors was reviewed by The JPAC Standing Advisory Committee on Tissues, Cellular Therapy Products (SAC TCTP) and other interested parties and it was decided that a steering group should be established to review whether this was appropriate. The FAIR III Steering Group included wide representation across the UK, from colleagues working within tissue and organ donation, patient and donor family representatives, groups with an interest in LGBT+ health, and academic colleagues.

The group looked at whether FAIR could be applied to tissue and cell donors using the FAIR I evidence base with an option to carry out further work if required. The group agreed that the FAIR I data collected from blood donors and members of the wider general population could be mapped to living donors. Many of the points raised in earlier discussions about acceptability of questions for blood donors also applied to living tissue and cell donors. The steering group was keen that donor selection for tissue and cell donors should be aligned with blood donors otherwise this could be seen as inequitable. As with blood donors, it was important that potential tissue and cell donors understood why these questions were being asked particularly the need for ensuring the safety of the recipient.

There are no specific restrictions regarding donations for haematopoietic stem cells in the same way as other living donors, instead a documented individual risk/benefit donor assessment is required. However, alongside the already more individualised risk approach to such donations it was acknowledged that the MSM and female partner of MSM questions would need to remain for some international recipients, to meet the requirements of other countries.

The discussions for deceased tissue donors were more complex with five options reviewed. It was quickly decided that not implementing FAIR in some form was not an option. The main concerns for deceased donors related to third party information: whether the person providing the information

about the donor required to ensure safe tissue donation would be able to answer additional questions about sexual behaviours, how 'unknown' answers would be managed and whether FAIR changes could disproportionately affect younger donors who are already scarce. Data were available from responses to organ donor risk assessments, including some organ donors who also donated tissues. These data provided information on how people answered current sexual behaviour questions, how often the person providing information about the organ donor for donation could not provide a response, and who was providing the information about the donor. These data and further discussions with the teams responsible for carrying out donor assessment gave reassurance that the number of 'unknown' answers would be small. The donor representative on the steering group raised concerns about the potential impact of telephoning family members using the additional FAIR questions so close to their relative's death. They felt the sensitive nature of the questions in this context would lead to donor loss as relatives would not want to be asked. However, the donation teams reported more sensitive questions are asked towards the end of the donor assessment, with a warning provided to the family member before going ahead to ask. Nurses are trained to deal with such sensitive questions with empathy and to pick up on cues and rarely lose families at that point, and rarely get complaints. There was no evidence from organ donor consent that family members disengaged or declined organ donation due to "sensitive questions" about their relative's sexual history although it was acknowledged that they may not always be able to answer all the questions.

For deceased tissue donors, applying FAIR to MSM only was considered because of concerns over potential donor losses of people who are currently eligible (heterosexuals having anal sex with new/multiple partners). This option was disregarded as inequitable and would not be in line with blood donation policy. Two options were discussed in detail, implementing FAIR in full or implementing all FAIR questions excluding anal sex. The latter could potentially result in donor loss as those donors with new or multiple partners in the previous 3-months would not be accepted. However, following discussions it was agreed that FAIR should be implemented in full for deceased donors but acknowledging that post implementation would be very important to ensure that there was not an adverse impact on donor acceptance rates.

1.1 Recommendations for living tissue donors

- Living tissue donors - surgical bone donors: FAIR to be implemented in full, i.e. the removal of the MSM and partner MSM questions and the addition of three new questions to all donors reporting sex: 1) treatment for gonorrhoea or syphilis in the last 12 months, 2) history of chemsex in the last 3-months, and 3) sex with a new or more than one partner in the last 3-months. If 'yes' to this last question, donors will be asked

if they had anal sex with their partner(s) regardless of whether they consistently used condoms. From this, donors who have had one sexual partner who was not new in the last 3-months are eligible to donate irrespective of gender, gender of partner or type of sex.

- Cord blood and stem cell donors: the group also agreed that FAIR could be implemented safely for cord blood and stem cell donors. The questions about MSM would need to remain for some stem cells donors, this information is not used for donor selection, but it is a requirement to allow the stem cells to be sent world-wide.
- The group acknowledged that implementation would require pre-donation information on rationale to help with consent, include a recipient focus and stakeholder engagement, as was the case for blood donors. A plan for monitoring and evaluation should be devised to include a 6-month and 12-month review.

1.2 Recommendations for deceased tissue donors

- Five options were reviewed, and three were excluded as not equitable, practical nor supported by evidence. Two options were discussed in detail, implementation of FAIR in full, and implementation of FAIR but without the anal sex question resulting in deferral of people with recent new or multiple partners. Following additional considerations of management of potential responses to FAIR question the group recommended that FAIR should be implemented in full.
- Where necessary and in exceptional circumstances donations could be issued by clinical concession if the donor did not meet the donor selection criteria.
- It is recommended that additional communications are prepared for donor families and staff and potential impact on donor deferral is monitored and consideration given to monitoring donor family experiences.
- The group acknowledged that implementation would include a recipient focus and stakeholder engagement, as was the case for blood donors.
- Post implementation monitoring should be devised to include a 6-month and 12-month review and capture the impact of the FAIR questions on donor deferrals in terms of reasons and numbers.

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2. Background and Introduction

2.1 FAIR I

In 2019, the FAIR I steering group took an evidence-based approach to reviewing whether a more individualised risk-based blood donor selection policy could be recommended in the UK. The work focussed on men who have sex with men (MSM) and whether changes to the then population-based donor selection criteria could be introduced to assess risk using a gender-neutral risk-based approach at an individual level. At the time, the donor selection guidelines deferred MSM from blood donation for 3-months from last sex with a man. The steering group, with representation from donors, recipients, and LGBTQ+ persons, initiated a programme of work to consider evidence of behaviours associated with acquiring blood borne infections (BBIs) and used both epidemiology and behavioural science to make recommendations as to donor eligibility.

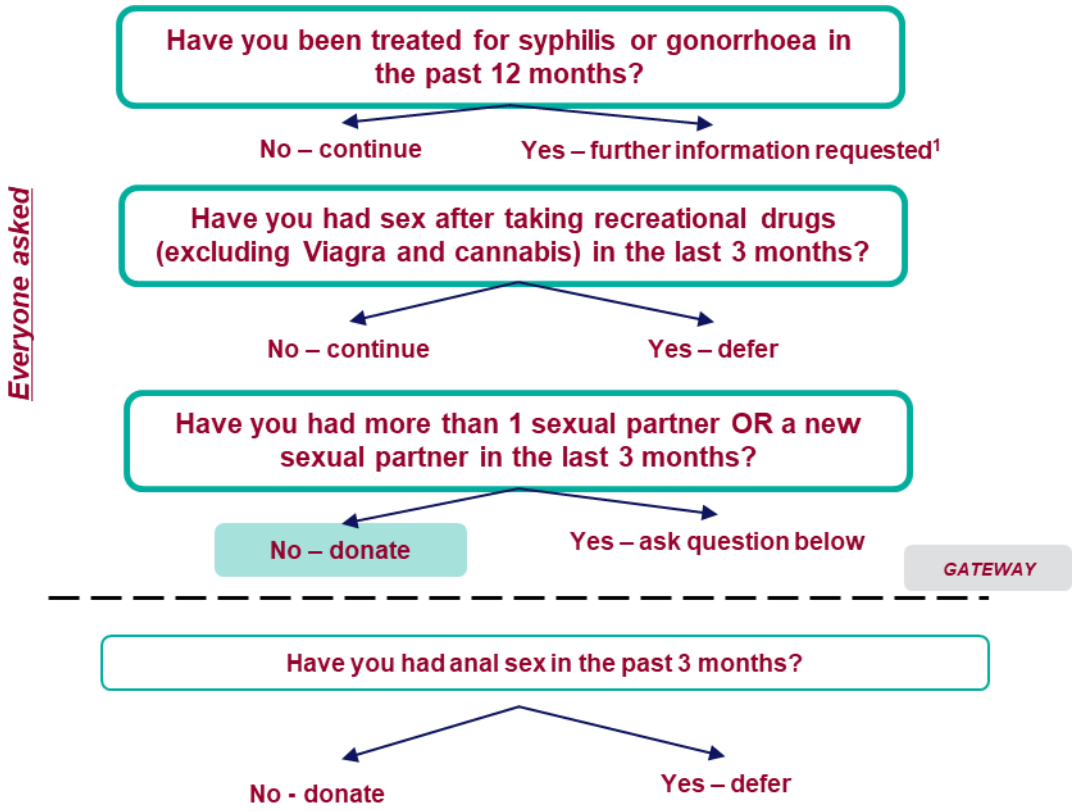
The epidemiological review looked at the literature relating to higher risk sexual behaviours and markers of risk, observed data in current donors and risk factors, and survey data on behaviours and acceptability of questions in current donors. The behavioural work included focus groups and surveys of a range of stakeholders including donors, potential donors, staff, MSM and recipients and assessment of reproducibility, acceptability, and robustness of potential questions. The work also explored the concept of risk and how communication with current and new donors could ensure that donors understand the importance of donor selection in maintaining blood safety and protecting blood recipients from infection.

In October 2020, the group submitted a report and recommendations to SaBTO. This included the proposed new questions for donors (Figure 1). These new questions would allow donors who have had only one sexual partner, where this sexual partner has been their only partner for more than 3-months, to be eligible to donate regardless of gender, gender of partner or type of sex. This would allow MSM in long-term partnerships to donate if they fulfilled all other donor assessment criteria. An additional question asked after the gateway question would allow some donors with new or multiple partners to be able to donate blood if they had not had anal sex in previous 3-months. Women who have sex with women remained eligible.

In addition to the specific proposals to the donor selection questions, FAIR also made several recommendations related to the process of donor selection. This included reiterating that although donations are tested for several blood-borne infections they are not tested for everything, and even very sensitive tests will not detect recent infections. It was recommended that donors should be encouraged to think about any recent higher risk exposures prior to donation and self-defer as

appropriate. In addition, the focus of donor selection processes should move away from donor risk to patient safety. FAIR also proposed further post-implementation work to ensure that there was no impact on blood safety nor other unintended consequences i.e., people previously safe to donate being unexpectedly excluded.

Figure 1: Algorithm for the proposed new FAIR questions



[1] *The donor will be asked additional questions: For past syphilis – permanent deferral. For past gonorrhoea – 3-month deferral. Note: new donors are asked an additional question about if they have EVER had syphilis, if yes, they will be permanently deferred*

A new donor questionnaire based on the FAIR changes for blood donors went live on 14th June 2021 in Scotland, Wales and England and Northern Ireland followed in August 2021.

Further work (FAIR II) resulted in the removal of a blood donation question which asked about sex with a partner who had ever had sex with someone in parts of the world where HIV is endemic including most countries in sub-Saharan Africa. This disproportionately affected donors who were from an African heritage. The four devolved administrations accepted the recommendation from SaBTO that this question could be removed if FAIR and the more-individualised risk-based assessment was introduced.

2.2 Legislation for tissue and cell donors in the UK

The EU Directive on Tissues and Cells (2004/23/EC) and its associated Commission Directives (2006/17/EC and 2006/86/EC) have been transposed into UK law as the Human Tissue (Quality and Safety for Human Application) Regulations 2007. These regulations lay down standards of quality and safety for all aspects of banking of human tissues and cells intended for human applications.

The key requirements for donor selection derive from Commission Directive 2006/17/EC (technical requirements for the donation, procurement and testing of human tissues and cells). This specifies that:

'The use of tissues and cells for application in the human body carries a risk of disease transmission and other potential adverse effects in recipients. That risk can be reduced by careful donor selection, testing of each donation and the application of procedures to procure tissues and cells in accordance with rules and processes established and updated according to the best available scientific advice. Therefore, all tissues and cells, including those used as starting material for the manufacture of medicinal products, to be used in the Community should meet the quality and safety requirements laid down in this Directive'.

The Human Tissue (Quality and Safety for Human Application) Regulations, 2007, as amended, specifies a range of allogeneic donor deferral criteria for donors of tissues & cells. These are set out in Annex A of the HTA 'Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment'. Regulatory requirements for donor testing are set out in Annex B of the Guide.

The regulatory requirement for donor selection, as set out in the HTA Guide is as follows:

Para 84: Selection criteria for donors must be based on an analysis of risks related to the application of the specific tissues or cells. Indicators of these risks must be identified by biological testing, review of the medical and behavioural history, physical examination, post-mortem examination (for deceased donors) and any other appropriate investigation

Para 85: Donors must be excluded from donation if any of the criteria in Annex A apply unless donation is justified based on a documented risk assessment approved by the DI (Designated Individual)

Para 86: There must be documented procedures for donor selection which set out the selection and exclusion criteria, the reviews, and investigations to be carried out and who is responsible for donor selection.

Annex A of this Guide includes the following criteria which are of relevance to this report:

1. Deceased donors:

1.1.6. - History, clinical evidence, or laboratory evidence of HIV, acute or chronic hepatitis B (except in the case of persons with a proven immune status), hepatitis C and HTLV I/II, transmission risk or evidence of risk factors for these infections.

1.1.9. - Evidence of any other risk factors for transmissible diseases on the basis of a risk assessment, taking into consideration donor travel and exposure history and local infectious disease prevalence.

1.1.10. - Presence on the donor's body of physical signs implying a risk of transmissible disease(s) that may be sufficient in themselves to exclude the donor or which must be assessed in the light of the donor's medical and personal history.

2.2. Allogeneic living donor

2.2.1. Allogeneic living donors must be selected on the basis of their health and medical history, provided on a questionnaire and through an interview performed by a qualified and trained healthcare professional with the donor, in compliance with point 2.2.2. This assessment must include relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases or health risks to themselves. For any donation, the collection process must not interfere with or compromise the health or care of the donor. In the case of cord blood or amniotic membrane donation, this applies to both mother and baby.

2.2.2. Selection criteria for allogeneic living donors must be established and documented by the tissue establishment (and the transplanting clinician in the case of direct distribution to the recipient), based on the specific tissue or cells to be donated, together with the donor's physical status and medical and behavioural history and the results of clinical investigations and laboratory tests establishing the donor's state of health.

2.2.3. The same exclusion criteria must be applied as for deceased donors with the exception of point 1.1.1. (1.1.1 is Cause of death unknown)

2.3 Previous reviews for tissue and cell donors in the UK

Following the emergence of HIV and evidence that the HIV virus could be transmitted by blood transfusion, donor selection criteria were introduced in 1983 for people who were thought to be at higher risk of acquiring HIV; these included men who have sex with men who at the time were permanently deferred from donating blood. The policy was reviewed in the mid-2000s but in 2010 the DHSC expert committee on the Safety of Blood, Tissues and Organs (SaBTO) set up a working

group to review the ongoing deferral of MSM. Changes were recommended allowing MSM who had not had sex with another man in the last 12 months to become eligible to donate blood. These changes were implemented in 2011 and discussion followed about whether these changes should also be applied to tissue and cell donors. SaBTO set up a working group to look at the donor selection criteria for both living tissue and cell donors and deceased donors of banked tissues. The group looked at risks for those viruses that are part of routine testing but also specific risks which would be of significance in these types of donations e.g., HHV8, and whether processing would reduce the potential risks from infection. Unlike blood donation there were already several donor groups where there was no specific deferral for MSM and where a more individualised assessment was already in place including haematopoietic stem cells donors, and donors of pancreatic islets and hepatocytes. In all these cases the MSM was not an absolute deferral unlike for banked tissues due to their life-saving nature and lack of supply. Following the review of 2013, SaBTO recommended that the tissue donor selection guidelines should be aligned with those for blood donors with a 12-month deferral for MSM, and for women with a male partner who had ever had sex with another man.[1] In 2016 SaBTO reviewed donor selection in relation to sexual behaviour and other higher risk behaviours associated with acquiring blood-borne infections. Again, a working group was set up to review the epidemiological evidence including impact of previous changes but also considered some behavioural aspects of donor selection. The group looked at donor selection for blood, tissue, and cell donors. The outcome of this review concluded that at that time population-based donor selection criteria should continue but with a 3-month deferral to be applied for MSM and women with partners who were MSM. This applied to living and deceased tissue donors but although information on sexual behaviours would be collected for stem cell donors, eligibility was based on information provided and potential match for a recipient. [2]

As noted above the most recent review of donor selection guidelines has recommended an approach based on epidemiological and behavioural evidence with a move away from population-based criteria to a more individualised approach, looking at individual donor behaviours in the context of what is known to increase risk of infection. It is desirable to have similar donor selection guidelines for blood and tissue donors and to use similar questions in assessing cell donors hence this assessment of whether the blood donor FAIR work can be applied to tissue and cell donors.

[1] Donor selection criteria for men who have had sex with men - GOV.UK (www.gov.uk)
[2] Blood, tissue and cell donor selection criteria report: 2017 - GOV.UK (www.gov.uk)

2.4 Scope of this review and Terms of Reference for FAIR III Steering Group

The FAIR III Steering Group was established at a meeting in September 2021. As with the previous FAIR work this was a multidisciplinary group with both patient and donor family representation. The full terms of reference and membership are included in Appendix 1.

Considerations were given to current legislation as described in section 2.2. It was acknowledged that donor selection criteria for tissues in the UK have closely aligned with those for blood unlike stem cell donors where there is already a more individualised approach to donor selection regarding sexual behaviours. In contrast to blood, the UK blood services are not the only provider of tissues to UK hospital, there are several private providers who are also regulated by the Human Tissue Authority (HTA).

For this review, tissue and cell products from UK donations were divided into two donor groups: living and deceased. Living donors include those who make donations of surgical bone and amnion, and haematopoietic stem cells (HSC) from related and unrelated donors, and from cord blood donors. Deceased tissue donors include those who give heart tissue, skin, cornea, bone, and tendons. Out of scope for this review were living or deceased donors who gave organs for direct transplant (not banked) and autologous donors of HSC.

Both donor groups were assessed and compared to blood donors in terms of demographics and rates of markers of infection detected on routine testing, along with the available information on the chance that testing does not identify an infection in a donor which could then enter the supply. The extent of sexual behaviours among the current donor population was explored. Current risk assessments regarding sexual behaviours were reviewed and options for FAIR were considered, taking into account potential issues of third-party information.

3. Donor assessments and options review

3.1 Living tissue donor assessment

3.1.1 Key points

- Living donors included in this report include donors of surgical bone, amnion, cord blood and haematopoietic stem cells (HSC)
- Routine infection surveillance systems are in place for living surgical bone and cord blood donors but there is no routine data available for HSC.
- Currently low rates of infections are detected in these donors, the risk of non-detection due to window period infections is decreased due to use of Individual NAT testing.

- Generally, donor selection criteria for blood and tissue donors are very similar for sexual behaviours. Stem cell donor are assessed differently, and data collected about behaviours is used to assess individual risk.
- There are different requirements in the international registries for asking stem cell donors about whether they are MSM or have partners who are MSM so this question would need to remain for some international recipients and the rationale communicated to the donor.
- The evidence from FAIR I regarding acceptability and reliability of questions is expected to map well to other living donors.
- Two options were considered - implement in full or do not implement.
- It is recommended that FAIR is implemented in full for living donors resulting in additional questions being asked and removal of the question about sex in areas of the world where HIV is endemic.
- It was acknowledged that most tissue donors have only one opportunity to donate.
- It is important to bear in mind the language to be used when asking the sexual behaviour questions.
- Data relating to tissue donor deferrals is not easily available. It is recommended that numbers and types of deferrals are monitored as part of the post implementation work and current surveillance systems used to assess risk of infection rates.

3.1.2 Donor demographic information

Data about living surgical bone (LSB) and cord blood (CB) donors in England is routinely collected by the NHSBT and UKHSA Epidemiology unit, which also collates data on blood donors through a parallel scheme. The demographic characteristics include gender and age, however ethnicity is not routinely recorded. Some data for stem cell and amnion donors are available but information is limited, these donors are not fully integrated into the surveillance scheme and are not reported upon here. Data about donations tested by SNBTS are not integrated into the surveillance scheme either; however, donors tested for donations made between 2018 and November 2021 are included in Appendix 1.

In 2020, there were 260 LSB donations and 141 CB donations made in England. Just over half LSB were female (57%) which was similar to blood donors, for both new donors and blood donors overall (55% in both groups). All CB donors identified as female. The age distribution of both LSB and CB donors was different to blood donors (Figure 2a and Figure 2b).

Most LSB donors are donating a femoral head when undergoing an elective primary hip replacement procedure, so that these donors are generally older than blood donors. In 2020, 91% of LSB donors

in England were over 55 years, compared to 28% of all blood donors and 9% of new blood donors. CB donors donate immediately post-partum and were all aged less than 44 years, compared to 78% of new blood donors identifying as female.

Figure 2a: The age distribution of living surgical bone and whole blood donors, England 2020.

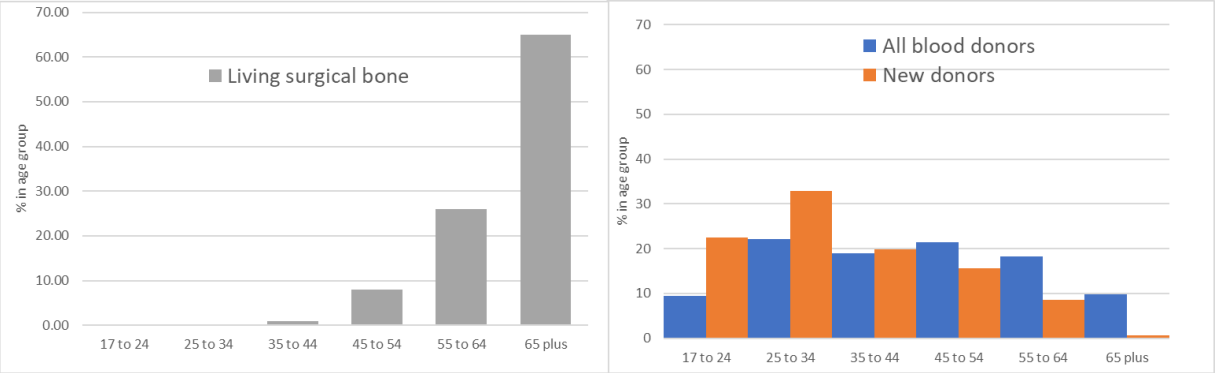
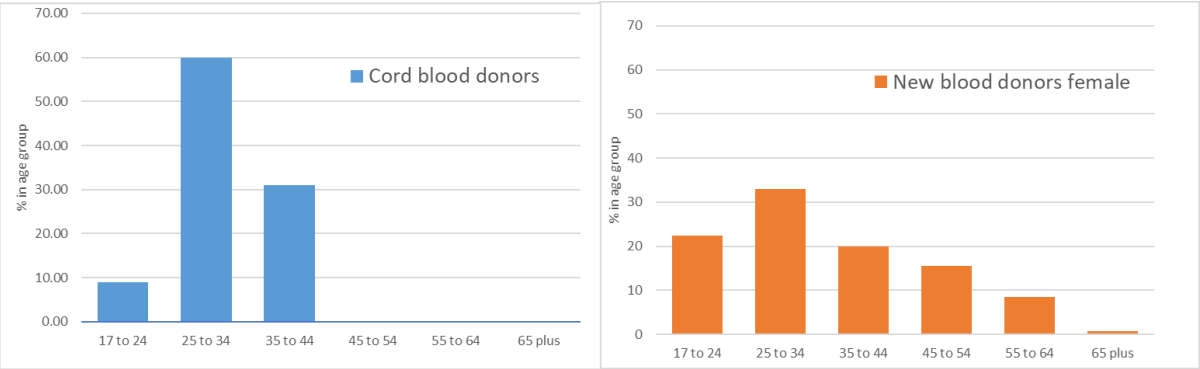


Figure 2b: The age distribution of cord blood donors and female new whole blood donors, England 2020.



Although no data were available on the demographics of stem cell donors, donations are made by individuals identifying as male and female and are between 17 and 55 years of age at registration.

3.1.3 Epidemiology of infections in donors detected on routine screening

LSB and CB donors are tested to the same protocol as blood donors for hepatitis B surface antigen (HBsAg), antibodies to hepatitis C (anti-HCV), combined antibodies/antigen to human immunodeficiency virus (HIV) types 1 and 2 (anti-HIV), treponemal antibodies (syphilis) and antibodies to human T-lymphotropic virus (HTLV) types 1 and 2 (anti-HTLV). In addition, anti-HBc and NAT for HBV, HCV and HIV are mandatory tests for tissue donors, with NAT tests performed in individual samples and not pooled. HEV NAT testing is also performed. Donations are processed and released if they meet the quality standards, and all the mandatory test results are negative for

current infection. CB donors are screened routinely for markers of HBV, HIV and syphilis, and sometimes HCV depending on additional donor history as part of antenatal testing and are then repeat tested on the day of donation, hence risk of undiagnosed blood borne viruses due to window period donations is reduced. For stem cells anti-HBs information is required for registries.

Data about donations tested by SNBTS are not integrated into the surveillance scheme, however, donors tested for donations made between 2018 and November 2021 are included in Appendix 1.2.

Infections are detected in very low numbers in both donor groups but because of the overall small number of donors we see higher rates than in blood donors, and for LSB older age groups are disproportionally affected. In 2020, no LSB or CB donors tested positive for markers of HBV, HCV, HIV, HTLV or syphilis. To allow comparison with blood donors we considered donations made in England by tissue donors between 2016 and 2020 (Table 1).

Table 1: Number of HBV, HCV, HIV, HTLV and syphilis positive living surgical bone and cord blood donors 2016 -2020 compared to positive blood donors

		HBV		HCV		HIV		HTLV		Syphilis		Total	
	Number	N	Rate per 100,000	N	Rate per	N	Rate per 100,000	N	Rate per 100,000	N	Rate per 100,000	N	Rate per 100,000
NHSBT 2020													
Living surgical bone (LSB) donors	260	0	-	0	-	0	-	0	-	0	-	0	-
Cord blood donors (CBD)	141	0	-	0	-	0	-	0	-	0	-	0	-
NHSBT 2016 - 2020													
LSB donors	2655	0	-	2	75.3	0	-	0	-	2	75.3	4	150.7
Cord blood donors	5590	3	53.7	0	-	0	-	0	-	5	89.4	8	143.1
NHSBT 2020													
DONORS	769,420	43	5.6	25	3.2	8	1.0	11	0	59	7.7	146	19.0
NEW DONORS	103,554	40	38.6	24	23.2	7	6.8	11	10.6	30	29	112	108.2
REPEAT DONORS	665,866	3	0	1	0.2	1	0.2	0	0	29	4.4	34	5.1
Rate ratio													
LSB 2016-2020 v all blood donors 2020			-		23.5		-		-		9.8		7.9
LSB 2016-2020 v new blood donors 2020			-		3.2		-		-		2.6		1.4
CBD 2016-2020 v all blood donors 2020			9.6				-		-		11.6		7.5
CBD 2016-2020 v new blood donors 2020			1.4				-		-		3.1		1.3

For this period, 4 LSB and 8 cord blood donors were found positive, approximating to rates of 150.7 and 143.1 per 100,000 respectively. These rates were around 8 -fold greater than blood donors overall, and 1.4 times greater than new blood donors.

None of these positive donors had evidence of recently acquired infections, and the syphilis antibodies detected in CB donors likely reflected past infections and gave low level reactivity, likely below the sensitivity cut-off for antenatal screening.

3.1.4 Risk of non-detection

On very rare occasions an infection in a tissue donor may not be detected if the donation is made during the window period, i.e., the time after infection when there is enough virus to be potentially transmitted but not to be detected by the assay in use. The rate of non-detection is estimated as the residual risk (RR) and expressed per 100,000 donors tested.

For tissue donors living in England, these were most recently estimated using the well-established window period methodology for HBV, HCV and HIV between 2013 and 2017. [3] For these calculations, incidence was derived by adjusting incidence in new blood donors by the prevalence ratio for tissue and new blood donors and multiplied by the duration of Window Period (WP) for Individual NAT (ID NAT) testing. These calculations demonstrated that using ID NAT, the RR of not detecting HBV, HCV or HIV WP donations was <1 in 100,000, with tissue recipients at greatest risk of non-detected HBV (0.34 per 100,000 donors). RR in LSB donors was approximately 2-fold greater than new blood donors. Despite the overall higher RR in tissue donors than new blood donors, there are far fewer tissue donations made each year and it is therefore less likely in any given year that we could expect to not detect a WP donation. These data were extrapolated to the 629 LSB donors tested by NHSBT in 2017 to approximate that it could be up to several 100 years before one HBV WP donation may not be detected. A new donor selection policy would impact on RR if there was a change in incidence of newly acquired infections in the WP.

Residual risks were not calculated for CB donors, due to the additional antenatal screening prior to day of donation repeat testing, no CB donors had evidence of recently acquired infection and therefore there were no data to be used in such a model.

3.1.5 Sexual behaviour data for tissue and cell donor population

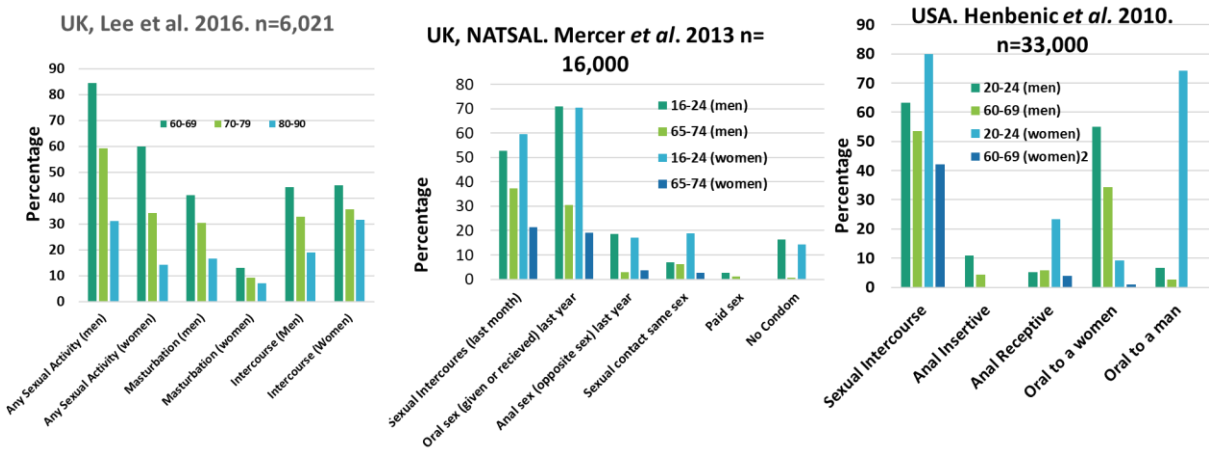
Of the LSB donors, 65% are over 65 years indicating a predominately older population. The literature on the sexual behaviours in older aged populations was reviewed to help inform the discussions

[3] Davison, K.L., Chandrasekar, A. & Brailsford, S.R. Re-assessing the risk of undetected HBV, HCV and HIV in deceased tissue and living surgical bone donors in England. *Cell Tissue Bank* **22,** 635–641 (2021). https://doi.org/10.1007/s10561-021-09927-7

around risk both of acquiring infection from sexual behaviours but also potential impact on donor loss if they would be deferred under the FAIR criteria as used for blood donors.

As people get older there is a reduction in frequency of all forms of sexual behaviour. This is due to health concerns and other behavioural reasons. Three key papers were found to be relevant, and the key data detailed below (Figure 3). Lee et al (2016) carried out a detailed analysis of 6,021 men and women aged 50 to 90 from wave 6 (2012/13) of the English Longitudinal Study of Ageing.[4] The figure reports general sexual activity in men (2745) and women (3456) in three age groups (60-69, 70-79, 80-90). 'Any sexual activity in the last year' declines over age for both men and women and is of lower frequency in women, and the same is true of masturbation and sexual intercourse.

Figure 3: Sexual activities in older people from three published studies in the UK and USA.



Similarly, data from Mercer et al report data from 15162 participants (6293 men and 8869 women) from NATSAL-3 in the UK.[5] As with the Lee et al study, we observe a decline by age, greater for women than men, with anal sex and same-sex contact of lower frequency when compared with those aged 16-24. A study by Henbenic et al (2010) of 5862 participants (men = 2933, and women =

[4] Lee, DM, Nazroo, J, O'Connor, DB orcid.org/0000-0003-4117-4093 et al. (2 more authors) (2016) Sexual Health and Well-being Among Older Men and Women in England: Findings from the English Longitudinal Study of Ageing. Archives of Sexual Behavior, 45 (1). pp. 133-144. ISSN 0004-0002

[5] Mercer CH, Tanton C, Prah P, Erens B, Sonnenberg P, Clifton S, Macdowall W, Lewis R, Field N, Datta J, Copas AJ, Phelps A, Wellings K, Johnson AM. Changes in sexual attitudes and lifestyles in Britain through the life course and over time: findings from the National Surveys of Sexual Attitudes and Lifestyles (Natsal). Lancet. 2013 Nov 30;382(9907):1781-94. doi: 10.1016/S0140-6736(13)62035-8. Epub 2013 Nov 26. PMID: 24286784; PMCID: PMC3899021.

2929) from the National Survey of Sexual Health and Behaviour in USA in 2009, again showed a decline in sexual activity with age, with anal sex of lower overall frequency.[6]

There were no data about new and/or multiple sexual partners in older age groups but given the above data it is likely these partnerships occur at a lower frequency than younger people. In contrast, 69% of CB donors are aged less than 34 years indicating a predominantly younger population and more closely aligned to new blood donors.

3.1.6 Current risk assessment forms

LSB, CB and stem cell donors in the UK are routinely assessed for donations using a donor risk assessment form. Seven donor risk assessment forms were reviewed here with respect to the setting where the assessment takes place, the sexual behaviours asked about, and the response options available. The forms are summarised in the table below (Table 2). The responses collected using these forms are not routinely available for review and are not reported here.

For LSB donors, assessment forms were obtained for NHSBT, SNBTS, Belfast HSCT and Leicester Bone and Tissue Bank (LBTB). Donor assessments take place either face to face in hospitals just before surgery, or on the telephone. Responses options are either 'yes' or 'no', with space to record further details as necessary. The forms do not collect gender specifically, except the LBTB form, but instead refer to gender later in the behaviour questions when asking about sex between men. With regards to past infections, questions are included about syphilis, except for SNBTS's form which asks more generally about any past STI, HIV, hepatitis and HTLV, but not specifically for gonorrhoea. PrEP use is included for all except LBTB, either within 3-months (Belfast), 12-months (NHSBT) or ever (SNBTS). Forms from SNBTS and NHSBT include a gateway question about sex within the previous 3-months before any further questions about sexual behaviours are asked. All assessments ask about sex in the last 3-months between men (MSM question), for women who have had sex with men who have ever had sex between men (FPMSM), and with other higher-risk partners (HRP), except LBTB, which asks about ever having sex with HRPs. Other HRP include people who are paid for sex, have ever injected drugs, have HIV/HTLV/hepatitis, and have had sex in sub-Saharan Africa. All forms ask about the donor themselves being paid for sex.

[6] Herbenick D, Reece M, Schick V, Sanders SA, Dodge B, Fortenberry JD. Sexual behavior in the United States: results from a national probability sample of men and women ages 14-94. J Sex Med. 2010 Oct;7 Suppl 5:255-65. doi: 10.1111/j.1743-6109.2010.02012.x. PMID: 21029383.

For NHSBT amnion and CB donors, the risk assessment forms are almost the same as for NHSBT LSB donors. The exceptions are for CB donors as follows: there is no gateway question about sex within 3-months, donors are asked about past gonorrhoea, PrEP within 3-months rather than 12-months and asked about sex with a male partner who had sex between men (FPMSM) within 12-months rather than 3-months.

For stem cell donors, assessment forms were obtained from the Welsh Bone Marrow Donor Registry (WBMDR), The National Marrow Donor Programme (NMDP) and Anthony Nolan (AN). All assessments take place on the telephone. Responses options are either 'yes' or 'no', with space to record further details as necessary. Only AN collects gender. With regards to past infections, questions are included about syphilis, HIV, hepatitis and HTLV but not gonorrhoea. PrEP use within 3-months is included for the WBMDR and AN. None of the forms have gateway questions and all donors are asked the sexual behaviour questions. The WBMDR assessment asks about sex within 12-months between men (MSM question), between women and men who have ever had sex between men (FPMSM question) and with other HRPs, and if they have ever been paid for sex. The NMDP assessment asks about sex between men (MSM question) within the last 5-years, and sex between women and men who have ever had sex between men (FPMSM question), with other HRPs, and if they have been paid for sex within the last 12-months.

Table 2: A summary of the pre-donation risk assessment questionnaires for living tissue and cell donors

Living tissue donors							Living cell donors			
DONOR POPULATION	**Surgical bone donor**	**Surgical bone donor**	**Surgical bone donor**	**Surgical bone donor**	**Amnion**		**Cord Blood and Tissue Donor**	**Stem cell**	**Stem cell**	**Stem Cell**
Source	NHSBT	SNBTS	Belfast HSCT	Leicester B & T Bank	NHSBT		NHSBT	Welsh BM Registry	National BM Prog	Anthony Nolan
Setting face to face (F2F)	Telephone	F2F or telephone	F2F	F2F or telephone	Telephone		F2F	Telephone	Telephone	Telephone
Response options	Y/ N and details	Y/ N and details	Y/ N and details	Y/ N and details	Y/ N and details		Y/ N and details	Y/ N and details	Y/ N/Not asked/Not answered/details	Y/ N and details
Gender	No [refers to M/F patients for MSM Qs]	No [refers to M/F patients for MSM Qs]	No [refers to M/F patients for MSM Qs]	Y	No [refers to M/F patients for MSM Qs]		No - asks for 'mother'/'father' names	No [refers to M/F patients for MSM Qs]	No [refers to M/F patients for MSM Qs]	Y
Syphilis ever	Y	ever STI	Y	Y	Y		Y	< 1 year	Y	< 1 year
Gonorrhoea < 3 months	Not asked	included in above	Not asked	Not asked	Not asked		Y ever	Not asked	Not asked	Not asked
HIV/hepatitis/HTLV ever	Y	Y	Y	Y	Y		Y	Y	Y	Y
PrEP	Y <12M	Y ever	Y <3M	Not asked	Y <12M		Y <3M	Y <3M	Not asked	Y <3M and current
Gateway sex <3 months	Y	Y	Not asked	Not asked	Y		Not asked	Not asked	Not asked	Not asked
MSM <3 months	Y	Y	Y	Y	Y		Not asked	< 1 year	< 5 years	Not asked
FPMSM < 3 months	Y	Y	Y	Y	Y		<1 year	<1 year	<1 year	Not asked
Donor been paid for sex	Y	Y <3M	Y <3M	Y	Y		Not asked	Y Ever	Y <5Y and <12M	Not asked
Sex with other HRP* <3 months	Y	Y	Y	ever	Y		Y	<1 year	<1 year	Y

MSM – men who have sex with men. FPMSM – female partner MSM. PrEP – Post exposure prophylaxis. *HRP – high risk partner includes MSM, paid for sex, person who injects drugs, has past HIV/HTLV/hepatitis and has had sex in sub-Saharan Africa.

3.1.7 Mapping evidence from FAIR in blood donors to living tissue and cell donors

FAIR in blood donors provided evidence that the donor selection questions (see section 2.1) were expected to be effective and reliable at identifying increased risk behaviours in donors and acceptable to donors and staff. This was key for assurance that changes would not impact on safety nor sufficiency of supply. The evidence came from the behavioural work which involved focus groups with a range of stakeholders including donors, potential donors, staff, MSM and patients, and surveys among the general population and current blood donors. The participants providing the evidence were from a broad range of ages and ethnic groups, and different genders, giving no reason to think that their responses couldn't be generalised to other donor populations.

3.1.8 Options for FAIR

The steering group was asked to consider two options in relation to living donors: to either not implement FAIR (option A) or to implement FAIR in full (option B), and to consider if there were any additional options for LSB, CB or stem cell donors. For each option, the impact on donor risk assessment process, potential impact on infectious disease risk, the setting for risk assessment, the supply, safety, and equity were considered along with the basis for making the change. The key points of the review of options A and B are summarised in the tables below. No other appropriate options were identified. In practical terms the two options would result in the following

- Option A - do not implement.
- Option B - implement FAIR to all. Remove questions to men about sex between men in last 3-months, and to women about their male partners in last 3-months having ever had sex between men. Remove question about partners from sub-Saharan Africa. Ask new questions about gonorrhoea and chemsex, and anal sex with a new and multiple partner(s) in last 3-months. If yes, defer.

For LSB donors (Table 3a), non-implementation of FAIR (option A) would mean the risk assessment process and donor selection policy regarding sexual behaviours would be unchanged; donors would continue to be selected on a population-based risk approach. Male donors would continue to be asked about male partners, and females would be asked about whether their male partners had ever had an MSM partner in the past. This would be different to the gender neutral, more individualised questioning of FAIR for blood donors and as such was considered inequitable between the two donor groups. Implementing FAIR in full (option B) was not expected to impact on the safety or supply of LSB. The evidence from blood donors both before and after FAIR implementation supported this, showing that the policy was acceptable and effective in accurately identifying individuals at risk. To date, May 2022, there was no increase in the number of blood donors with

evidence of newly acquired infection. The policy was expected to map well to the LSB donors, as older people were represented in the original FAIR work. In addition, given the older age of LSB donors and evidence from the literature that sexual activity reduced with age it is suggested that the number of new and multiple sexual partners might also be reduced in LSB with the expectation that few donors would need to be asked about anal sex.

Applying FAIR would not require any additional changes in the donation process or testing. However, as for blood donors, the marketing and communications to donors and training of staff to explain the relevance of the change was key prior to implementation.

Table 3a: Review of option A and option B of FAIR implementation for living surgical bone and amnion donors

	A – do not implement	B – implement FAIR	Considerations
Donor risk assessment	Syphilis ever Gateway Q - Sex < 3-months? If yes, ask sex <3-months for MSM, FPMSM, PrEP, HRP, syphilis?	Remove MSM, FPMSM, partner SSA Add <3-months Gonorrhoea, Chemsex, Add <3-months PrEP? If yes - DEFER Add <3-months new or multiple partner – if yes, anal sex? If yes - DEFER [Add syphilis ever for SNBTS and HRP < 3 months for Leicester BB]	Marketing/comms
Infectious risk mitigation	Individual NAT testing, and anti-HBc, limited processing for some products	No change	
Setting	Telephone or face to face prior to donation	No change	New pre-donation information required
Supply	<2000 year	No change	No data on amnion donors available
Safety	Low rates of infections detected, single sample NAT testing, anti-HBc. Current residual risk 3-fold higher than blood donors	No change	Postimplementation monitoring
Equity	Selecting on sexuality. Different to current blood donors	Selecting on an individual's sexual activity And is the same policy as blood donors	
Basis for policy	Population based risk	Evidence from blood donors the policy will effectively, reliably and accurately identify individuals at low risk .	Expected to map well 55+ represented in FAIR

Table key: MSM – men who have sex with men. FPMSM – female partner MSM. PrEP – Post exposure prophylaxis. *HRP – high risk partner includes MSM, paid for sex, person who injects drugs, has past HIV/HTLV/hepatitis and has had sex in sub-Saharan Africa.

Similarly for CB donors (Table 3b), not implementing FAIR (option A) would mean the donor selection policy regarding sexual behaviours would be unchanged and is considered inequitable for reasons already discussed. Implementing FAIR in full (option B) is not expected to impact on the safety or supply of CB donors. CB donation is made in the antenatal setting, with antenatal screening for HBV, HIV and syphilis offered early in pregnancy before the consent process begins and gives rise to the extremely low level of infection detected on day of donation testing in this group. Most CB donors identify as female and are similar in age to blood donors who identify as female. As such the evidence from FAIR is expected to map well and therefore no unforeseen impact is anticipated. As discussed above, the new policy would not require any changes in the donation process or testing; however, pre-implementation training, marketing and communications needs to be considered.

Table 3b: Review of option A and option B of FAIR implementation for cord blood donors

	A – do not implement	B – implement FAIR	Considerations
Donor risk assessment	Syphilis ever No gateway question Ask sex <12months for FPMSM, <3 months HRP	Remove FPMSM, partner SSA Add <3-months Gonorrhoea, Chemsex, Add <3-months PrEP? If yes - DEFER Add <3-months new or multiple partner – if yes, anal sex? If yes - DEFER	Marketing/comms
Infectious risk mitigation	Individual NAT testing, and anti-HBc	No change	
Setting	Telephone or face to face prior to donation	No change	New pre-donation information required
Supply	<1000 year	No change	
Safety	Low rates of infections detected, single sample NAT testing, antiHBc.	No change	Antenatal testing in place
Equity	Selecting on sexuality Different to current blood donors	Selecting on an individual's sexual activity And is the same policy as blood donors	
Basis for policy	Population based risk	Evidence from blood donors the policy will effectively, reliably and accurately identify individuals at low risk .	Expected to map well

Table key: MSM – men who have sex with men. FPMSM – female partner MSM. PrEP – Post exposure prophylaxis. HRP – high risk partner includes MSM, paid for sex, person who injects drugs, has past HIV/HTLV/hepatitis, had sex in sub-Saharan Africa.

For stem cell donors (Table 3c), not implementing FAIR (option A) would again mean the donor selection policy regarding sexual behaviours would remain unchanged. However, while the policy in this setting is based on population risk, the risk assessment process itself is more individualised than the pre-FAIR policy for blood donors as all stem cell donors have a face-to-face interview with more detailed questioning in relation to sexual activities. Surveillance data for stem cells were not available for this policy review but anecdotally it is known that this approach gives rise to very few

infections in stem cell donors, and seroconversions detected in pre-donation samples are extremely rare.

As for the LSB and CB donors, implementing FAIR in full (option B) is not expected to impact on this as the evidence gathered from blood donors maps well to the stem cell donor population. Given the more individualised approach to selecting stem cell donors there is opportunity to discuss recipient safety ahead of donation. A further consideration for stem cells is ensuring that the supply for international recipients is maintained, and to do this the MSM question would need to remain for international recipients. However, the rationale for asking this question could be included in donor information

Table 3c: Review of option A and option B of FAIR implementation for stem cell donors

	A – do not implement	B – implement FAIR	Considerations
Donor risk assessment	Syphilis ever for National Bone Marrow Registry and Welsh BM PrEP Sex <3 months HRP **Anthony Nolan – no MSM Q**	Remove FPMSM, partner SSA Add <3 months Gonorrhoea, Chemsex, Add <3 months PrEP? If yes - DEFER Add <3 months new or multiple partner – if yes, anal sex? If yes - DEFER	MSM question will remain for international bone marrow donors Marketing/comms
Infectious risk mitigation	Individual NAT testing, and anti-HBc	No change	
Setting	face to face prior to donation /transplant. More than one donor may be considered	No change	New pre-donation information required
Supply	NK	No change	
Safety	Low rates of infections detected, single sample NAT testing, antiHBc.	No change	
Equity	Selecting on sexuality Different to current blood donors	Selecting on an individual's sexual activity And is the same policy as blood donors	
Basis for policy	Population based risk assessment with some more individualised questioning	Evidence from blood donors the policy will effectively, reliably and accurately identify individuals at low risk	FAIR expected to map well

Table key: MSM – men who have sex with men. FPMSM – female partner MSM. PrEP – Post exposure prophylaxis. *HRP – high risk partner: includes MSM, paid for sex, person who injects drugs, has past HIV/HTLV/hepatitis and has had sex in sub-Saharan Africa.

Three of the LSB donor risk assessment forms include a gateway question asking about sex in the previous 3-months. Those donors who report that they have not had sex in the last 3-months would not be asked further sexual behaviour questions. This could be considered for other living donors.

3.2 Deceased tissue donor assessment

3.2.1 Key points

- Surveillance data are available on the epidemiology of infection in deceased tissue donors. Overall rates of infections are higher than blood donors but newly acquired infections are rare. ID NAT is mandatory for these donors.
- Donors are older than blood donors with 80% over 55 years of age.
- The type and frequency of sexual behaviour changes within different age groups. Although evidence is lacking on the number of new and multiple sexual partners, it is likely that higher risk sexual behaviours are lower in these older donors.
- Tissue donor assessments may be carried out by SNODs, Tissue Donor Co-ordinators or the NRC, some tissue donors are also organ donors.
- The organ donor risk assessment form MaSH is used for all deceased donors.
- There were no data on the types of sexual behaviour disclosed by people consenting for tissue donation, but data were available from people consenting for organ donation where >90% were able to respond to questions about recent sex.
- Concerns were raised about the sensitive nature of the questions and whether these could be answered accurately or would be too intrusive. Donation staff were confident that FAIR questions could be asked and that various sources could be used to complete answers in the majority of cases.
- Where necessary and in exceptional circumstances donations could be issued by clinical concession if the donor did not meet the donor selection criteria.
- Five options were reviewed, and three excluded as not equitable, practical, nor supported by evidence. Two options were discussed in detail, implementation of FAIR in full, implementation of FAIR but without the anal sex question resulting in deferral of people with recent new or multiple sexual partners.
- Following additional considerations of management of potential responses to FAIR question the group recommended that FAIR should be implemented in full.
- It is recommended that additional communications are prepared for donor families and staff and potential impact on donor deferral is monitored, and if possible, the experience of donor families.

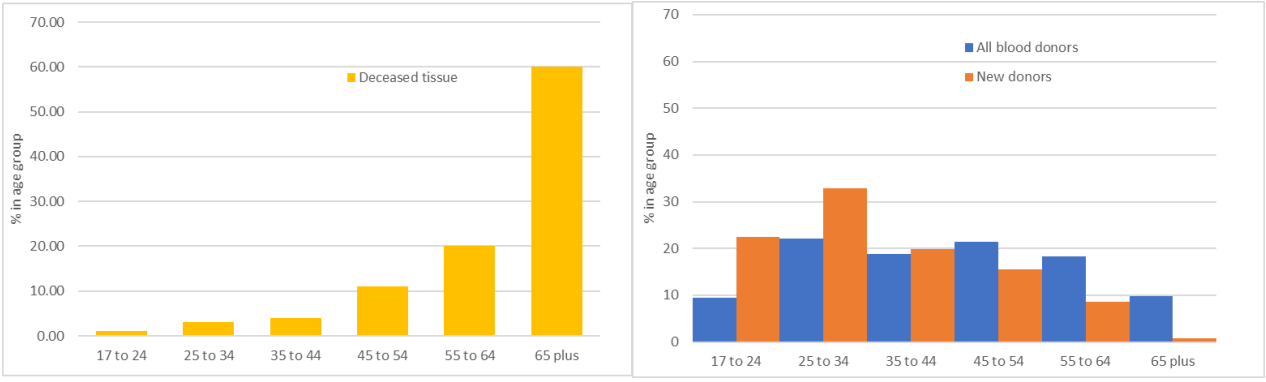
3.2.2 Donor demographic information

Data about deceased tissue donors (DT) in England are routinely collected by the NHSBT/UKHSA Epidemiology unit. The demographic characteristics include gender and age, however ethnicity is not

recorded. Data from Scotland are reported in Appendix 1, section 1.2, although not described here in detail, tissue data are collated.

In 2020, there were 2424 deceased tissue donors donating in England, 60% identified as male compared to 45% of new and total blood donors. The age distribution of DT donors was different to blood donors (Figure 4). In 2020, 80% of DT donors in England were over 55 years, compared to 28% of all blood donors and 9% of new blood donors, and 60% of DT donors were over 65.

Figure 4: The age distribution of deceased tissue donors and whole blood donors, England 2020.



3.2.3 Epidemiology of infections in deceased tissue donors

DT donors are tested and released to the same protocol as blood donors as described earlier with additional routine testing for hepatitis B anti-core antibodies, and with NAT tests performed in individual samples rather than pooled.

In 2020, 8 donors tested positive for markers of HBV, HCV, HIV, HTLV or syphilis, equating to an approximate rate of 330 per 100,000 donors (Table 4). This rate is around 19-fold greater than blood donors overall, and 3-fold greater than new blood donors. Over the 5-years from 2016 to 2020, markers of HBV have been most commonly detected.

Table 4: Number of HBV, HCV, HIV, HTLV and syphilis positive deceased tissue donors 2016 – 2020 compared to positive blood donors during 2020, NHSBT.

		HBV		HCV		HIV		HTLV		Syphilis		Total	
	Number	N	Rate per 100,000	N	Rate per 100,000	N	Rate per 100,000	N	Rate per 100,000	N	Rate per 100,000	N	Rate per 100,000
NHSBT 2020													
Deceased tissue donors	2424	5	206.3	0	0	0	0	1	41.3	2	82.5	8	330
NHSBT 2016 - 2020													
Deceased tissue donors	15541	27	173.7	8	51.5	0	0	2	12.9	19	122.3	56	360.3
NHSBT 2020													
DONORS	769,420	43	5.6	25	3.2	8	1.0	11	0	59	7.7	146	19.0
NEW DONORS	103,554	40	38.6	24	23.2	7	6.8	11	10.6	30	29	112	108.2
REPEAT DONORS	665,866	3	0	1	0.2	1	0.2	0	0	29	4.4	34	5.1
Rate ratio													
deceased tissue 2016-2020 v all blood donors 2020			31.0		16.1		-		-		15.9		19.0
Deceased tissue 2016-2020 v new blood donors 2020			4.5		2.2		-		-		4.2		3.3

3.2.4 Risk of non-detection

The risk of non-detection of WP infections in tissue donors has been described in section 3.1.4. The most recent calculations made in England between 2013 and 2017 included DT donors.[7] These calculations demonstrated that using ID NAT, the RR of not detecting HBV, HCV or HIV WP donations from DT donors was <1 in 100,000, with tissue recipients at greatest risk of non-detected HBV (0.74 per 100,000 donors). RR in DT donors was approximately 5-fold greater than new blood donors. The RR estimates were extrapolated to the 3329 DT donors tested by NHSBT in 2017 to approximate that it could be up to 41 years before one HBV WP donation may not be detected in a DT donor. As discussed for LSB donors, a new donor selection policy would impact on RR if there was a change in incidence of newly acquired infections and subsequent increase in WP infections.

3.2.5 Sexual behaviour data for deceased donor population

The majority (80%) of DT donors are over 55 years. As discussed earlier in section 3.1.5, as people get older there is a reduction in frequency of all forms of sexual behaviour. Although data about the

[7] Davison, K.L., Chandrasekar, A. & Brailsford, S.R. Re-assessing the risk of undetected HBV, HCV and HIV in deceased tissue and living surgical bone donors in England. *Cell Tissue Bank* **22,** 635–641 (2021). https://doi.org/10.1007/s10561-021-09927-7

frequency of new or multiple sexual partners in older people are not available, it is expected to be at a lower frequency than younger groups.

3.2.6 Current risk assessment forms

The form used to assess deceased people for organ and tissue donation in the UK is the NHSBT's Medical and Social History Questionnaire (referred to as MaSH), used by all tissue banks. The steering group reviewed this with respect to the setting where the assessment takes place, the sexual behaviours asked about, and the response options available. The form is summarised in the table below (Table 5).

Table 5: NHSBT's medical and social history questionnaire (MaSH) for deceased tissue and organ donors

	MaSH form
Setting	F2F for donors for organs and tissues. Telephone for tissues only
Responder	Family/Not Known/Nearest relative (relationship to donor recorded)
Response options	N or Y or unknown
QUESTIONS INCLUDED:	
Gender	No [refers to male/female patients]
Infections	
STI (not specified) ever	Yes
HIV/hepatitis/HTLV ever	Yes
PrEP	Yes - ever
Gateway Qs - Sex ever, sex <3-months	Yes
If yes:	
Sex between men - MSM <3-months	Yes
Female partner of MSM (FPMSM) 3-months	Yes
Sex with other HRP* <3-months	Yes

*Table key: MSM – men who have sex with men. FPMSM – female partner MSM. PrEP – Post exposure prophylaxis. *HRP – high risk partner: includes MSM, paid for sex, person who injects drugs, has past HIV/HTLV/hepatitis and has had sex in sub-Saharan Africa.*

Deceased donor assessment forms are normally completed by the person giving consent/authorisation for donation, often a member of the donor's family or next of kin/nearest relative. The consent process and donor assessment are carried out either face to face with the specialist nurses in organ donation (SNODs) for donors giving organs and tissues, or on the telephone with specialist staff in tissue services at the National Referral Centre (NRC) or Tissue Donor Co-ordinators in Scotland for those donating tissues only. Response options are either 'yes',

'no', or 'unknown' with space to record further details as necessary. The form does not collect gender specifically but instead refers to gender later in the behaviour questions when asking about sex between men. With regards to infections, questions include knowledge of current or past syphilis, HIV, hepatitis and HTLV but not gonorrhoea (but asks "Ever had a sexually transmitted disease"), the use of PrEP at any time is also recorded. The form includes a gateway question for sex ever before any further questions about sexual behaviours are asked, and another question about sex within the last 3-months before questions about recent sexual behaviour are asked. These are: sex in the last 3-months between men (MSM question), between women and men who have ever had sex with another man (FPMSM), and with other higher-risk partners (HRP). Other HRP include people known to be positive for HIV, hepatitis or other STI and paid for sex.

Data collect through the MaSH forms were available from the Organ and Tissue Donation and Transplantation Team (OTDT) for people assessed for deceased organ and tissue donation. Data for donors only donating tissues are not stored electronically and were not easily accessible to the steering group. The data from OTDT were used to assess the relationship to the donor of the key person involved in consent and donor assessment, the extent of certain behaviours within the donor population, and the percentage reporting 'unknown' responses. These data include organ donors and donors who donated both organs and tissues.

The relationship to the donor of the key person involved in the assessment for UK deceased organ donors is listed below (Table 6). In 2020 and 2021, most (53-54%) were a spouse or partner, including other close family members (child, sibling, or parent) and they accounted for almost all (99%) of the responders.

Table 6: Relationship of key person consenting and completing risk assessment for UK deceased organ donation, 2020 and 2021

	2020		2021	
Relationship of key person	**n**	**%**	**n**	**%**
Spouse of partner	339	53%	908	54%
child	93	15%	239	14%
Brother or sister	56	9%	151	9%
Parent	126	20%	331	20%
Cousin	5	1%	3	0%
Niece or nephew	3	0%	8	0%
Friend of longstanding	11	2%	25	1%
Aunt or uncle	0	0%	5	0%
Grandparent	0	0%	3	0%
Stepparent	0	0%	1	0%
Not reported	1	0%	5	0%
Total	634		1679	

The tables below (Table 7a and Table 7b) show the responses to questions about the donor's sexual behaviour (numbered on the MaSH form as questions 35, 36a, 36b, and 37a-i, available in Appendix 2). Over 92% were reported to have ever had sex, and this was reported with high certainty at 97% (3% reported 'unknown'). The 'ever had sex' question is used as a gateway to ask additional questions including if the donor was paid for sex within the previous 3-months and if they had ever had a 'sexually transmitted disease'. The data here indicate these questions were asked of almost all donors in 2019-2021. Being paid for sex was rare at 0.3% and reported with a similarly high certainty (97% known/not applicable, 3% unknown). Having had a 'sexually transmitted disease' was reported at 4.7%, with slightly lower certainty (92% known/not applicable, 8% unknown).

Almost 40% of donors were reported to have had sex within 3-months, with slightly lower certainty at 91% as ~9% reported 'unknown'. Again, this question is a 'gateway' to some more in-depth sexual behaviour questions, and this response rate indicates that one in three relatives are currently asked about these behaviours, however this is likely to be higher for younger donors.

For the 40% of donors reported to have had sex within 3-months, increased risk sexual behaviours were reported for < 1% (Table 8). For questions regarding MSM, sex between men was reported for 0.5%, sex between women and MSM for <0.1%, and sex with someone who had HIV, HTLV, or hepatitis B or C for 0.3%. All the increased risk behaviours were reported with certainty above 96%, the highest certainty was for responses to the question regarding MSM (around 99% known/not applicable, 1% unknown).

Table 7: The MaSH assessment responses from relatives to questions about sexual behaviours: a) ever had sex b) sex within 3-months for UK deceased organ donors, 2019-2021

Year of interview	Has your relative ever had sex – consensual or otherwise?*						
	No		Yes		Unknown		Total
	N	%	N	%	N	%	N
2019	115	4.9	2177	92.3	67	2.8	2359
2020	83	4.7	1633	92.3	53	3.0	1769
2021	69	4.5	1424	92.8	42	2.7	1535
Total	267	4.7	5234	92.4	162	2.9	5663

Year of interview	Did your relative have sex, consensual or otherwise in the last 3 months?*									
	No		Yes		NA		Unknown		Total	
	N	%	N	%	N	%	N	%	N	
2019	1249	52.9	883	37.4	16	0.7	211	8.9	2359	
2020	909	51.4	698	39.5	12	0.7	150	8.5	1769	
2021	793	51.7	588	38.3	11	0.7	143	9.3	1535	
Total	2951	52.1	2169	38.3	39	0.7	504	8.9	5663	

Table 8: The questions about specific sexual behaviours and responses from relatives to questions for UK deceased organ donors, 2019-2021

Question number on MaSH		Question	Yes		No		NA		Unknown		Total
			N	%	N	%	N	%	N	%	N
Q36		Sexually Active Ever	3810	92.3	198	4.8	0	0.0	120	2.9	4128
	Q36a	Been Paid For Sex last 3 months	12	0.3	3669	88.9	9	0.2	120	2.9	3810
	Q36b	Sexually transmitted disease (STD)	196	4.7	3280	79.5	4	0.1	330	8.0	3810
Q37		Sexually active last 3 months	1581	38.3	2158	52.3	28	0.7	361	8.7	4128
	Q37a	Sex between men	20	0.5	939	22.7	610	14.8	12	0.3	1581
	Q37b	Sex between women and men who were MSM	1	0.0	653	15.8	876	21.2	51	1.2	1581
	Q37c	Sex with HIV or HTLV Positive	6	0.1	1454	35.2	1	0.0	120	2.9	1581
	Q37d	Sex with hepatis B or C	10	0.2	1446	35.0	1	0.0	124	3.0	1581
	Q37e	Sex with someone with STD	30	0.7	1394	33.8	1	0.0	156	3.8	1581
	Q37f	Sex with someone who has Been Paid For Sex	16	0.4	1454	35.2	1	0.0	110	2.7	1581
	Q37g	Sex IV Drug User	21	0.5	1442	34.9	0	0.0	118	2.9	1581
	Q37h	Sex AIDS/HIV Area	10	0.2	1467	35.5	1	0.0	103	2.5	1581
	Q37i	Sex Travel Illness	2	0.0	1481	35.9	0	0.0	98	2.4	1581

Responses to Q36a_b and Q37a_i have only been included where Q36 and Q37 = yes

3.2.7 Mapping evidence from FAIR in blood donors to deceased tissue donors

Evidence from the psychological work stream of FAIR suggested blood donors would find the proposed donor selection questions to be acceptable and they would be able to give accurate and reliable responses. Furthermore, post-implementation in blood donation there have been no increases in complaints about the new donor selection process. However, the steering group acknowledged that the previous FAIR work had not considered third party responses resulting in a review of whether additional evidence was required (see section 3.2.9)

3.2.8 Options for FAIR

The steering group was asked to define possible options for implementing FAIR for deceased tissue donors using the evidence base collated for FAIR in blood donors. For each option, the impact on the donor risk assessment process, infectious disease risk, method of risk assessment, supply, safety, and equity were considered.

The following options were considered:

- Option A – do not implement.
- Option B – implement FAIR to all donors. Remove questions to men about sex between men in last 3-months, and to women about their male partners in last 3-months having ever had sex between men. Remove question about partners from sub-Saharan Africa. Ask new questions about gonorrhoea and chemsex, and anal sex with a new and multiple partner(s) in last 3-months. If yes, defer.
- Option C – implement FAIR for all donors but exclude the anal sex question.
- Option D – only implement FAIR including anal sex question to donors who are consented by their partner.
- Option E – consider alternative questions to FAIR to identify lower risk donors.

The key points of the review of option A and option B are summarised below (Table 9).

For option A, not implementing FAIR would mean the risk assessment process and donor selection policy regarding sexual behaviours would be unchanged; donors would continue to be selected on a ‘population risk’ based approach (Table 9). This would be different to the gender neutral, more individualised questioning of FAIR for blood donors and as such is considered inequitable between the two donor groups. On this basis option A was rejected for deceased tissue donors.

Option D was also rejected. Concerns were raised about the FAIR approach not being applied in an equitable manner, but in addition this was not a workable option as partners of less than 3-months

are not considered be the right person to answer questions about long term medical and social history of the deceased donor.

For option E, the steering group did not identify any other options that could be applied.

Table 9: Review of option A and option B of FAIR implementation for deceased tissue donors

	A – do not implement	B – implement FAIR	Considerations
Donor risk assessment	Past HIV/HTLV/hepatitis, PrEP ever? Gateway Q – sex ever? If yes, ask if paid for sex, past STI? Gateway Q - sex < 3-months? If yes, ask about sex <3-months for MSM, FPMSM, HRP	Remove MSM, FPMSM After gateway Q sex <3-months .... Add <3-months Gonorrhoea, Chemsex, Add <3-months PrEP? If yes - DEFER Add <3-months new or multiple partner – if yes, anal sex? If yes - DEFER	3rd party responses not been assessed for reliability, accuracy or acceptability
Infectious risk mitigation	Individual sample NAT testing and anti-HBc	No change	
Setting	Telephone, or face to face if organ donor too	No change	New pre-donation information required
Supply	~3500 year NHSBT	Gains include FPMSM and MSM in established relationships (MSM <3m 0.5% OTDT) Losses applied to Gonorrhoea, Chemsex, PrEP and anal sex with new/multiple partner	Potential for clinical concession
Safety	3-fold higher than blood donors, lower than other countries. Residual risk 7-fold higher than blood donors	Likely no change	Post-implementation monitoring
Equity	Selecting on sexuality Different to current blood donors	Selecting on an individual's sexual activity Similar policy to blood donors	
Basis for policy	Population based risk	Evidence from blood donors the policy will effectively, reliably and accurately identify individuals at low risk	Enough assurance from blood donor data?

*Table key: MSM – men who have sex with men. FPMSM – female partner MSM. PrEP – Post exposure prophylaxis. *HRP – high risk partner: includes MSM, paid for sex, person who injects drugs, has past HIV/HTLV/hepatitis and has had sex in sub-Saharan Africa*

One of the key considerations for implementing FAIR in full was whether the person providing consent/authorisation and completing the donor questionnaire would be able to answer some of the questions about sexual behaviour. Of particular concern was the risk that the FAIR questions could lead to more uncertainty than current questions and potentially increase the number of donor deferrals. While the evidence reviewed in the blood donation setting pre- and post-FAIR implementation suggested the questions were effective and reliable in identifying individuals at lower risk of acquiring infection and acceptable to donors and staff, this was not enough assurance for the deceased donor setting. Concerns were raised about asking the donor's family and/or friends about sexual behaviours related to anal sex. The steering group suggested more work was required to assess the impact of these additional FAIR questions on 3rd party responses.

Option C was considered as an alternative approach to option B where the FAIR questions were asked but not the additional anal sex question. Although this would reduce deferrals arising from uncertainty about how to respond to the anal sex question it would result in an overall increase in deferrals above those under option B as here all donors with new or multiple sexual partners would become ineligible to donate, irrespective of type of sex.

For options B and C, it was noted that the impact would likely be greater among younger donors who could be valuable multi-tissue donors, and already there are not sufficient young donors to meet clinical requirement. For these situations, a process for clinical concession for donation is already in place which could potentially reduce the impact of these deferrals.

Despite the concerns raised above and after discussion, the steering group concluded that the evidence for FAIR was based upon implementing the policy in full rather than any mixed approach to applying the questions. On this basis option C was disregarded and option B was agreed as the recommended approach for implementation in deceased tissue donors

3.2.9 Assessing the reliability of third-party responses for deceased tissue donors

In order to assess the reliability of third-party information collected in the MaSH forms it was necessary to find out how staff assessing deceased tissue donors would manage 'unknown' responses to the FAIR questions, and the potential impact of implementing FAIR on deferrals. The opinions of academic colleagues Dr Leah McLaughlin (University of Bangor) and Professor Eamonn Ferguson (University of Nottingham and the steering group psychologist member) experienced in qualitative research related to blood and organs donors were sought.

The psychologist on the steering group commented that 'no' and 'unknown' answers are hard to differentiate, particularly when answered by a third party. An option to explain why the answer is "unknown" e.g., living in different city, not in recent contact, could be considered. To minimise unknown responses, there was discussion around giving a steer towards answering FAIR questions "to the best of your knowledge" with options as 'yes' or 'no' only. Or potentially informing relatives that a confirmatory 'yes' response to a behaviour question will exclude a donor, but unknowns are not treated as a 'yes'.

Three tissue donation staff (including two members of the Steering Group) all experienced in donor consent were asked for clarification on how current questions regarding increased risk sexual behaviours were dealt with (questions 35, 36a, 36b, and 37a-i on the MASH form, appendix 2). They were also asked for their views on how the new FAIR questions would fit into the existing consent

process particularly around how ‘not known’ responses would be managed, and if they had any concern around implementing FAIR.

Management of donor risk assessment responses

The questions asked of staff members and a summary of their responses are given in Table 10. All three confirmed that a ‘not known’ response from families would be managed as ‘yes’ and deferred however this would only be after more discussion and as appropriate follow up with SNODs (if relevant), next of kin, partners, family members or friends.

As the data collected for deceased tissue donors are not stored electronically, it was not possible for the staff members to easily determine the extent of ‘not known’ responses. However, to help in this assessment, one staff member reviewed individual MaSH forms for 10 recent deceased tissue donors and found no ‘not knowns’ for the sexual behaviour questions. They also reviewed the last 100 referrals and had five donors deferred on unknown sexual or high-risk behaviour history. In three of these cases, the identified nearest relative had minimal contact or were estranged and had no recent knowledge of any donor activities. In one case there was no family or friend of longstanding identified and in another during formal discussion of risks with the closest relative they disclosed that the potential donor had had multiple sexual partners in previous 3-months.

Table 10: Summary of staff views on responses to current sexual behaviour questions for deceased tissue donors and implanting FAIR questions

Consider the CURRENT increased risk sexual behaviours questions (MaSH form 35, 36a, 36b, and 37a-i)	**Summary of responses**
1. Are we correct to assume a 'not known’ would be manged as a ‘YES’ and the donor would be deferred, is this the same for all these Qs?	Yes - after more discussion/follow up
2. For 'not known’ responses, would you seek further information, and if so what/where, or accept as ‘unknown’?	Yes - SNOD/next of kin/partners/friends
3. Can you give us an estimate of the proportion of 'not known’s you get for deceased tissue donors? Do you think this would this be like deceased organ donors?	No routine data available Difficult to know if the data would reflect that from organ donors
Consider the inclusion of FAIR questions for deceased tissue donors	

[In the last 3-months, have you had Chem sex? Gonorrhoea? Sex with a new, or multiple partners – if yes, anal sex?]	
4. Would responses be handled in the same way?	Yes
5. Do you think we would get more 'not known' responses?	No/unlikely - except anal sex
6. Do you think FAIR will increase deceased tissue donor pool? Why, why not?	No Not sure
7. Do you have any concerns about introducing FAIR?	No
8. Is there anybody else you think we need to speak to on impacts of adding FAIR Qs.?	Discussed with clinical leads and support staff and tissue donor co-ordinating managers

When asked to consider the inclusion of FAIR questions for the deceased tissue donor assessment, all three staff members confirmed the responses would be handled in the same way as the current questions, i.e., seeking further clarification or information elsewhere as required. There was no expectation that FAIR would increase the proportion of 'not known' responses except perhaps for the anal sex question, nor that FAIR would increase deceased tissue donation. There were no concerns among these staff members about including the FAIR questions for deceased tissue donors, and their views reflected those of others in tissue services including clinical leads and support staff and tissue donor co-ordinating managers across the UK.

Conclusion

Despite the concerns raised above and after discussion, the steering group concluded that the evidence for FAIR was based upon implementing the policy in full rather than any mixed approach to applying the questions. On this basis option C was disregarded and option B was agreed as the recommended approach for implementation in tissue donors.

No further work was required at this time in relation to third party information although it is important that post-implementation data could be collated and reviewed to monitor the impact of the change.

4. FAIR III Report Appendix 1

4.1.1 Appendix 1.1 : Terms of Reference for the Steering Group FAIR III for Tissue and Cell Donors

October 2021

1. MEMBERSHIP

A quorum will be six members, excluding the chair. Deputies can attend meetings on behalf of members. In the absence of the Chair, the Deputy Chair will chair meetings unless the Group decide otherwise.

Affiliations of members	
Interim Associate Medical Director: Manufacturing and Logistics	NHSBT/ UKHSA
Senior scientist NHSBT/ UKHSA Epidemiology Unit	NHSBT/ UKHSA
SACTCTP Chair	NHSBT
SACCSD Chair	SNBTS
Scientist NHSBT/ UKHSA Epidemiology Unit	NHSBT/ UKHSA
Director of Policy and Communications	NAT
Donor representative or donor family	
Head of Media & PR	Freedom to Donate
Professor of Psychology	University of Nottingham
Policy Officer, Trans Staff Network Group Co-Chair	Stonewall
	WBS
Associate Director of Policy and Research	Stonewall
Director of Policy and Communications	NAT
Consultant Microbiologist	NHSBT
Interim Medical Director for Cells, Apheresis and Gene Therapy	NHSBT
Assistant Director, Organ Donation	NHSBT

Affiliations of members	
Assistant Director Tissue Eye Services	NHSBT
National Referral Centre Matron	NHSBT
Consultant in Transfusion Medicine, WBS, Medical Director, Welsh Bone Marrow Donor Registry	WBS
Clinical Scientist (H&I), Head of Birmingham Centre and Chair of the LGBT+ Network	NHSBT
	Health Northern Ireland
SACTCTP – BSBMT Clinical Lead, Therapeutic Apheresis Services	SNBTS
Medical Director	THT
Lead Nurse Tissues, Cells & Advanced Therapeutics	SNBTS
OTDT clinical governance group - Chair	NHSBT
Senior Clinical Development Scientist	NHSBT
Cord Blood Bank Director	NHSBT
Patient representative	NHSBT
Corporate Communications Manager	NHSBT
Consultant & Clinical Lead, Tissues, Cells & Advanced Therapeutics	SNBTS
Policy and Campaigns Officer	NAT
Scientist NHSBT/ UKHSA Epidemiology Unit	NHSBT/UKHSA
Donor Experience	NHSBT
Consultant Haematologist	NHSBT

2. ACCOUNTABILITY AND AUTHORITY

The Group was self-proposed. The Group is accountable to the Medical & Research Director of NHS Blood and Transplant (NHSBT). The Group via the membership will report to the Clinical Directorate and Blood Donation Senior Management Teams within NHSBT, JPAC, and to medical directors of the other UK blood services. There are currently no other groups accountable to this group. The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) will be updated of any developments by the Consultant in Epidemiology and Health Protection and /or other relevant medical directors.

3. ROLE

The steering group member(s) will provide input (based on their direct experience and knowledge) to the development, monitoring and delivery of a package of work to assess whether all or some of FAIR can be directly implemented for tissue and cell donors. Through regular attendance at meetings and timely response to actions, members will:

- **Provide strategic leadership and oversight of the FAIR III work package**
- Provide advice on the prioritisation of work to ensure timely delivery, and guidance on any changes as the work develops
- Encourage new areas of work, including collaborations with others, e.g. UK Health Security Agency (UKHSA) [previously known as Public Health England (PHE)], tissue services outside of the UK blood services, patient groups
- Contribute to the dissemination of information for wider use.

4. FUNCTIONAL ARRANGEMENTS

The secretary will circulate papers to the members of the group at least five working days prior to the meeting. Circulation of papers will be restricted to members of the group. The minutes will be sent to the Group, the Medical Director of NHSBT and any others, as identified by the Group.

5. DECLARATIONS OF INTEREST

On joining the group, and subsequently on an annual basis, all members will be asked to declare relevant interests in writing. A library of interests will be maintained by the secretary. At the commencement of each meeting, the Chair will ask all members to identify any agenda items where a potential conflict may exist with members' outside interests (declared or undeclared). Such issues will be recorded in the minutes of the meeting. A declaration of an interest should not restrict an individual member from participating in discussion of an agenda item.

The definitions of interests that are considered relevant in this context are as follows:

Personal interest: An association exists between an influential individual and a company. The association includes a personal financial benefit to the individual (or close relative), e.g. income from patent/licence associated with a novel test kit or the ownership of shares in the company.

Organisational interest: As association exists between an influential individual and a company. The association includes no personal financial benefit, but the organisation for which that individual works benefits financially from the association, e.g. money (or goods in kind) paid to the organisation for test kit development work. This would exclude kit evaluation by an organisation on behalf of a supplier of a contracted basis.

Professional interest: An association exists between an influential individual and a company.

The association includes no personal or organisation financial benefit.

Note: Reimbursement of reasonable costs associated with, e.g. lecturing abroad, are not categorised as being “financial benefit”.

6. MEETINGS

Two meetings will be held, with additional meetings held at the discretion of the Chair.

Standing agenda items will be:

- Matters arising/action points

7. REVIEW

The terms of reference will be reviewed by the members of the group at least yearly

4.1.2 Appendix 1.2: SNBTS living and deceased tissue donations

Table 1: SNBTS living and deceased tissue donations tested and donors confirmed positive for markers of infection, from 2018 to November 2021

Donor type	2018	2019	2020	2021 to Nov 2021
Bone	742	677	360	395
Stem Cells	401	382	325	386
Deceased	38	25	26	21
Islets	20	18	11	17
Reproductive tissues	10	7	8	10
Organs	63	101	96	89
Cellular therapy	20	23	48	54
Gametes				18
Positive donors				
HBV	null	null	null	1 Autologous SC
HCV	null	**1 bone**	null	
HCV	1 OD	2 OD (known positive)	1 OD (known positive)	1 OD (known positive)
HCV	2 CT (known positive)	2 CT (known positive)	null	1 CT (known positive)
HIV	1 SC (known pos)	1 OD (known positive)	null	null
HTLV	null	null	null	null
Syphilis	1 OD	**1 bone**	**1 bone**	1 Autologous SC, 1 gamete

5. FAIR III Report Appendix 2 – donor risk assessment forms

Continue on the following pages for:

- NHSBT Surgical bone donor
- SNBTS bone donor
- Belfast Health and Social Care surgical bone donor
- Leicestershire bone and tissue bank
- NHSBT amnion donor
- NHSBT cord blood and tissue donor
- Welsh Bone Marrow Registry
- National Marrow Donor Program
- Anthony Nolan
- NHSBT deceased donor medical and social history questionnaire (MaSH)

Consent To Record	Yes	No
Do you agree to the conversation about donation between me (name of HCP) of NHSBT and you being recorded? May we use this recording and case detail for our records?		
For the purpose of this recording can you give me your full name, address and GP details **The recording will be stored as proof of the information that I give you and of the medical information and consent which you give to me.**		

First Name:	Surname:	Date of birth:	Age:
Hospital:	Date (of interview):	Donation Number: *(Donation Team Only)*	

Donor medical history	Yes	No
1. What is the reason for your hip operation?		
2. Have you ever suffered from any other bone or joint diseases? Give Details		
3. The next questions are random but are the questions which would normally **STOP** you from donating: i. Have you ever had a blood transfusion? (Where, When, What for?) ii. Have you ever been diagnosed with Cancer? iii.Have you ever had an organ or tissue transplant? Including IVF with donated eggs?		
4. Do you have any medical conditions requiring medication or regular check-ups?		
5. Give Details of **ALL** medications		
6. Have you suffered from any serious illnesses such as • Chronic or Autoimmune Disease? • Hepatitis, Jaundice, liver Disease or Alcohol related Disease? • Been investigated for cancer?		
7. Have you had any health problems related to exposure to toxic substances such as pesticides, lead, mercury, asbestos?		
8. Have you ever had any surgery or operations? (Spinal, Brain, other hip?, (which may have used dura mater? Where, When)		

Donor Name:	**DOB:**	**Yes**	**No**
9. Do you suffer from any other type of brain disease such as Alzheimer's, Parkinson's or Dementia? Or have you suffered from recent memory loss or confusion?			
10. To your knowledge has anyone in your family suffered with Creutzfeldt Jacob Disease (CJD)			
11. Have you ever received human pituitary extracts e.g.: growth Hormones or fertility treatment or test injections for hormone imbalance?			
12. Have you come into contact with any infectious diseases in the last month? (Covid exposure)			
13. Have you had any immunisations or travel vaccines in the last 2 months? Have you come into contact with the small pox vaccine in the last 2 months?			
14. In the last 3 months have you had any tattoos, body piercings, Botox injections, acupuncture, colonic irrigation, faecal transplantation or any other treatments or injuries involving piecing of the skin?			
15. In the last 24 months have you been bitten or scratched by any animal (strays, pets, wild farm or ticks) a human Bats or been in close contact with bats? OR had Rabies			
16. Have you **EVER** been outside the UK? If No go to Q22			

Donor Name:	**DOB:**	**Yes**	**No**

17. Since this time last year have you been outside the UK? **YES / NO**

When did you return from your last trip?

Country……..…..Resort/City/region……When (month/year)……..

Country…… Resort/City/Region……..When (month/year)……..

Do you intend to travel before your operation? Where? When? **YES / NO**

Country……..…..Resort/City/region……When (month/year)……..

Country…… Resort/City/Region……..When (month/year)……..

Please give as much travel information as possible.

18. Have you ever had malaria? Or Zika Virus?		
19. Have you had an unexplained fever, within 6 months of return of travel abroad		
20. Have you ever lived or stayed outside the UK for a continuous period of 6 months or more? Please state country/region and year		
21. Have you ever lived or worked in rural Central or South America or Mexico for a continuous period of 4 weeks or more?		
22. Were you or your mother born in central or south America or Mexico?		

Please use this space for any further medical information or any further comments

_____

_____

_____

_____

_____

_____

_____

Donor Name:	**DOB:**

YOU MUST NOT DONATE YOUR BONE IF:

- You are HIV or HTLV positive or think you may be
- You know you carry the Hepatitis B or C virus
- If you have ever been diagnosed with Syphilis
- If you have had sex with someone who has had Viral Haemorrhagic fever

Do any of the above apply to you? **YES** **NO**

You must not donate your bone if in the last 12 MONTHS:

- You have injected yourself or been injected with habitual drugs of addiction
- Taken medication to prevent HIV infection e.g.: PrEP pre/post exposure prophylaxis

Have you ever had sex? **YES** **NO**
If YES:

- Have you been given payment for sex with money or drugs? Yes / No
- Ever had a sexually transmitted infection Yes / No

Have you had sex in the last 3 months? **YES** **NO**
If yes, have you had sex with:

- (for male patients) another man
- (For female patients) a man who has ever had sex with another man
- Anyone who is HTLV or HIV positive
- Anyone who has Hepatitis
- Anyone who has a sexually transmitted disease
- Anyone who has ever been given payment for sex with money or drugs
- Anyone in the last 12 months has injected or been injected with non-prescription drugs including performance enhancing drugs or injectable tanning agents
- Anyone who could have had sex in any parts of the world where AIDS/HIV is common (this includes most countries in Africa
- Anyone who has developed an illness related to travel such as ZIKA

Do any of the above apply to you? **YES** **NO**

Is there any other information you feel we need to know **YES** **NO**

Section D Medical history authorisation

Additional tests required **MAT** **T-CRUZI** **WNV** **N/A**

Is Medical History Acceptable? **Yes** **No** (If NO state reason)……

Is more information required? **Yes** **No** (if yes fill in communication form)

Refer to TES Medical staff / Clinical support Nurses? **Yes** **No** (if yes fill in FRM911)

Medical history taken by: …… Signature:……Date:……

Final Medical Authorisation

Additional Tests Required **MAT** **T_CRUZI** **WNV** **N/A**

Medical History **Pass** **Fail** (if fail state reason)……

Name……Signature ……..Date:……
Any further comments:

SNBTS BONE DONOR MEDICAL HISTORY / CONSENT FORM

Name:	CHI Number/DOB:	GP:
Address:	Telephone No:	Address:
	Hospital:	
Postcode:	Consultant:	Tel No:

In all questions - if the response is yes - please indicate the question number and detailed response in the comments box below. Detailed responses should include date/s of what, where, when and for how long.

HAVE YOU EVER:	Yes	No
1. Had any operations, serious illness, chronic condition, or major accident?		
2. Had health problems due to exposure to toxic substances such as pesticides, lead, mercury, gold, asbestos?		
3. Had cancer, investigations for cancer, unplanned weight loss?		
4. Had brain or spinal surgery?		
5. Had or think you might have had a bone, skin, ocular or other tissue graft/transplant?		
6. Had or think you might have had a blood transfusion or other blood product?		
7. Been told not to donate blood?		
8. Had jaundice, hepatitis, tuberculosis, brucellosis or any other serious infection?		
9. Received human pituitary extracts e.g. growth hormones, fertility treatment, or test injections for hormone imbalance?		
10. Had bone or joint disease other than osteoarthritis?		
11. Are you taking any medication or other treatments (including anything not prescribed by a doctor, or bought online/over the counter, both for treatment and prevention)?		
12. Have you ever had any medication for acne, psoriasis or prostate problems or to prevent HIV?		
13. Are you currently seeing or waiting to see anyone about any aspect of your health?		
14. Have you had any vaccinations in the past 2 months?		
15. Do you currently have or have you recently had a virus or infection of any type, including diarrhoea?		
16. Have you been in contact with anyone with an infection in the past month?		
17. Have you had memory loss, unsteady gait, confusion or any type of brain disease?		
18. Been told that you are at risk of CJD or has anyone in your family had CJD?		
19. **IN THE LAST YEAR:** have you been bitten or scratched by any animal/insect? Have you ever been bitten or in close contact with bats anywhere in the world? Have you ever been bitten by any other mammal outside the UK?		
IN THE PAST PAST 3 MONTHS HAVE YOU:		
20. Had acupuncture, a tattoo, piercing to any part of your face/body, botox, cosmetic treatment/surgery, colonic irrigation or faecal microbiota treatment?		
21. Had an injury that may have put you at risk from acquiring Hepatitis or HIV?		

TRAVEL HISTORY - HAVE YOU:	Yes	No
22. Ever visited South America, Central America or Southern Mexico for a period of 1 month or more?		
23. Ever stayed outside the UK for a continuous period of 6 months or more?		
24. Ever had Malaria or an unexplained fever which you could have picked up while travelling?		
25. Been outside the UK in the last year including for work?		
26. If yes were you unwell while travelling or within 1 month of returning to the UK?		
27. Were you and/or your mother born outside the UK?		
28. Do you plan to go abroad prior to your operation?		
LIFESTYLE:		
29. Are you or do you think you might be HIV or HTLV positive?		
30. Have you ever had Hepatitis or do you think you might have Hepatitis now?		
31. In the last 12 months have you injected or been injected with illegal non-prescribed substances? Includes performance enhancing substances or injectable tanning agents.		
32. Have you ever had a sexually transmitted disease?		
33. Have you ever had sex with anyone who has been diagnosed with a Viral Haemorrhagic Fever?		
34. Have you been sexually active in the past 3 months? **If No this is the end of the questionnaire.**		
35. In the last 28 days have you had sex with anyone who has had Zika Virus?		
36. In the last 3 months have you been given payment for sex such as with money or drugs?		
Have you had sex in the last 3 months with:		
37. (for males) another man?		
38. (for females) a man who has ever had sex with another man?		
39. Anyone who is HIV or HTLV positive?		
40. Anyone who has hepatitis?		
41. Anyone who has a sexually transmitted disease?		
42. Anyone who has ever been given payment for sex such as with money or drugs?		
43. Anyone who has ever injected, or been injected, with non prescription drugs, including performance enhancing substances or injectable tanning agents?		
44. Anyone who has ever had sex in parts of the world where AIDS/HIV is very common (includes most of Africa)?		

I understand this questionnaire and to the best of my knowledge all the information I have given is correct. I consent to my blood being typed, tested for infection (such as hepatitis, HIV, HTLV and syphilis) and stored for possible future testing. I understand that if there is infection, I will be informed of the results either directly, through the hospital medical team or my GP. I consent to SNBTS staff reviewing my medical notes and contacting my GP if required, to obtain relevant information to ensure the safety of my donation. I voluntarily donate my bone to SNBTS for patient treatment & consent to its storage. If the bone is found to be unsuitable for therapeutic use, I consent that it may be used for research, audit, education, training, quality assurance and performance assessment or disposed of in a lawful manner. I consent that information about me will be held by SNBTS for several years and made available in strict confidence to other healthcare staff if required.

Donor Signature:

Consented by Face-to-face/Recorded Conversation (delete non applicable)
(I have consented this donor in compliance with the HTA Guidance on Consent)

Date:

Signature of person obtaining consent:

Comments

	FEMORAL HEAD 1 TISSUE LABEL 1	FEMORAL HEAD 2 TISSUE LABEL 2 (if applicable)

Belfast Health and Social Care Trust
caring supporting improving together

Musgrave Park Hospital

Surgical Bone Donor Medical/Lifestyle Risk Assessment

- Potential donors should read the bone donation leaflet before being approached about donation.
- Please ensure sections A, B and C of this questionnaire are fully completed.
- Please elicit as much information as possible. Consult medical notes for clarification if available.
- Please do not use abbreviations when describing conditions and operations.
- Please consult the Tissue Donor Selection Guidelines as required.
- If you have any questions or would like advice, please contact the Bone Bank Co-Ordinator.

Section A: Donor details

Use addressograph-otherwise write in capitals	Reason for operation:	Barcode number:
Surname: _____ First names: _____ Address: _____ H and C Number: _____		

Check Identity

Medical history taken, patient's identity confirmed and armband checked:

Name:_____ Signed: _____ Date: _____

Section B: Donor medical history

	Yes	No	Details:
1. Have you ever had an organ or tissue transplant, or prior to 1992, any surgery to the brain or spine?	☐	☐	
2. Have you ever had any other operations, scopes, key hole surgery or suffered from any serious illnesses?	☐	☐	
3. Do you currently suffer from any medical conditions requiring medication or regular check ups?	☐	☐	
4. Have you ever been diagnosed with, or investigated for cancer?	☐	☐	
5. Were you treated with growth hormone before 1987?	☐	☐	

Section B: Donor medical history (continued)			
	Yes	**No**	**Details:**
6. To your knowledge, have you or anyone in your family suffered with Creuztfeldt Jakob Disease (CJD)?	☐	☐	
7. Have you ever suffered from any bone or joint disease? Including Rheumatoid Arthritis?	☐	☐	
8. Have you received a blood transfusion, organs, bone, tissue, or corneal graft since 1980?	☐	☐	Give dates:
9. In the last 3 months, have you had acupuncture, tattooing, ear/body piercing, or cosmetic treatment that involved piercing the skin? Have you taken Body Building Drugs or used injectable tanning agents?	☐	☐	Procedure: _____ _____ Date: _____ Name and address of practitioner: _____ _____ _____
10. Have you had any immunisations or vaccinations in the last 8 weeks?	☐	☐	
11. Have you had an injury, such as being nicked by a needle, which would put you at risk of hepatitis or HIV infection?	☐	☐	Date: _____ Treatment: _____ _____
12. In the last 12 months have you obtained a dog or human bite?	☐	☐	
13. Have you ever had Hepatitis, jaundice, liver disease, tuberculosis or brucellosis?	☐	☐	If yes, at what age and any diagnosis?
14. Were you born outside the UK or Ireland?			
15. Have you ever travelled or lived outside Western Europe, North America, Australia or New Zealand?	☐	☐	
16. Was the visit within the last 12 months?	☐	☐	If yes, please go to Q16.
17. Have you lived for longer than six months in any country where there is malaria?	☐	☐	
18. Have you ever had malaria?	☐	☐	
19. Have you ever had an unexplained fever whilst abroad or within 6 months of return to the UK?	☐	☐	

Section B: Donor medical history (continued)			
	Yes	**No**	**Details:**
19. Have you ever visited Central or South America? Did you live / work in a rural area for 4 weeks or more?	☐	☐	If yes, list dates/place, ask about primitive living conditions and/or sleeping out in the jungle.
20. Where you or your mother born in Central or South America?	☐	☐	If yes, please give place:
21. Do you suffer from any unusual symptoms? eg. recurrent infections, night sweats or swollen glands?	☐	☐	If yes, when and what diagnosis was made?
22. Have you suffered any significant weight loss recently?	☐	☐	If yes, do you know why?
23. Have you ever had potential ingestion of/or exposure to a substance such as: Cyanide, Lead, Mercury or Gold in a dose that could endanger your health?	☐	☐	If yes please list:
24. Are you on any medication at present?	☐	☐	
25. Have you ever suffered from an alcohol related disease?	☐	☐	
26. Have you ever attended a sexual health clinic or been treated or investigated for any sexually transmitted disease?	☐	☐	
27. Have you ever received treatment for Syphilis in past?	☐	☐	

Section C: Lifestyle Risk Factors (All potential donors must complete this section)

There are a number of infections, which can be transmitted through bone grafting. Your blood will be tested but in rare cases may be negative, even though infection is present. All donors are therefore asked to read this information carefully.

You should not volunteer to donate if you have ever had syphilis (even if fully treated) as our blood test will be positive and we will not be able to use your bone. Please do not offer to donate bone if you think you need an HIV/AIDS, Hepatitis or HTLV test.

You must not donate bone if you are:

- HIV positive.
- HTLV positive.
- a Hepatitis B carrier.
- a Hepatitis C carrier.

You must not donate bone if:

- You are less than 12 months after stopping habitual use of injected drugs of addiction.

You must not donate bone for at least 3 months if you have:

- Received money or drugs for sex.
- You have injected or been injected with non-prescription drugs, even if only once. This includes body building drugs or injectable tanning agents.
- Taken medication to prevent HIV infection (pre/post exposure prophylaxis PrEP/PEP).

You must not donate for at least 3 months after sex with (even if you used a condom or other protective)

- (If you are a man) another man.
- (If you are a woman) a man who has ever had oral or anal sex with another man.
- A partner who is, or you think might be HIV positive, HTLV positive, Hepatitis B or C carrier or infected with Syphilis.
- A partner who has received money or drugs for sex.
- A partner who has injected non-prescription drugs.
- A partner who has, or you think may have been sexually active in parts of the world where HIV is very common. This includes most of Africa. There are exceptions so please ask.
- A partner with haemophilia who has been treated with clotting factor concentrates.

Do any of the above apply to you? ☐ **Yes** ☐ **No** (Tick as appropriate)

For Musgrave Park Hospital Bone Bank use only

Medical history passed: ☐ **Yes** ☐ **No**

If No, state reason and intended fate of donation:

Name: _____ Signed: _____ Date: _____

LEICESTER BONE & TISSUE BANK
UHL NHS TRUST

Medical history / lifestyle assessment

Operation Date:

Hospital:

Patient name:

M/ F D.O.B:

Hosp/NHS no:

Address:

Phone:

Key points about bone donation

- During your hip replacement the top of your thigh bone (femoral head) is taken away and replaced with an artificial one. Some of the bone which has to be taken away is good bone. This bone can be used to help others instead of just disposing of it.

- Some people may not be accepted as bone donors, in a similar way that not everyone can be a blood donor. We wouldn't be able to accept donors if, for instance they'd had any type of cancer in the past or certain infections.

- Just like blood donors, we need to determine if bone donors are in a high risk group for HIV/AIDS. So some of the information we require may seem very personal, but this is necessary to comply with current regulations.

- If you decide you don't want to go ahead it is very easy to say "No" and no further questions will be asked. You can withdraw your consent to being a bone donor at any point up to the time your bone is used. This will not affect your treatment in any way.

- Stop me at any time if you have any questions

For telephone consent only	**Yes**	**No**
Do you agree to this conversation about your medical history and lifestyle being recorded?		

Medical history	Yes	No	Details
1. Have you ever been diagnosed with cancer or leukaemia?			
2. Have you: a) had a blood transfusion in the UK since 1980? b) had a blood transfusion anywhere outside the UK at any time?			
3. Have you been diagnosed with: a) rheumatoid arthritis? b) Parkinson's disease? c) multiple sclerosis? d) any autoimmune disease?			
4. Have you been diagnosed with a condition affecting the bones, for example, Perthe's or Paget's disease?			
5. a) Have you been diagnosed with porphyria or liver disease? b) Have you had hepatitis B or C or unexplained jaundice?			
6. Have you had any serious disease affecting your kidneys?			
7. Have you had a recent infected skin rash, for example, shingles?			
8. Have you ever been diagnosed with: a) typhoid? b) brucellosis? c) toxoplasmosis? d) rabies? e) meningitis? f) tuberculosis (TB)? g) HIV? h) syphilis or any other sexually transmitted disease?			
9. Have you been in contact with anyone with an infectious disease in the last 8 weeks?			
10. In the last 8 weeks: a) Have you had any vaccinations including smallpox? b) Have you had contact with someone who has had a smallpox vaccination?			
11. a) Have you ever consulted a doctor about memory loss or confusion? b) Have you or anyone in your immediate family (parent, brother, sister or child) been diagnosed with CJD, Alzheimers or dementia?			
12. Have you had an organ or tissue transplant of human or animal origin? for example, cornea			

Medical history	Yes	No	Details
13. Have you ingested, or been exposed to, a substance that has affected or could endanger ……your health such as cyanide, lead, mercury or ……gold?			
14. Have you had surgery for a tumour or cyst on the brain or spine before 1992?			
15. Have you had hormone treatment for infertility before 1985?			
16. Were you treated with growth hormone before 1985?			
17. **For women:** Have you received a donated egg, embryo or sperm since 1980?			
18. Have you ever taken regular steroid treatment (other than inhalers, or creams for skin conditions)?			
19. Have you had any recent illnesses including treatment with antibiotics or drugs, other than for your hip?			
20. Have you had any unexplained weight loss?			
21. Have you had any hospital/ healthcare treatment, operations or investigations not already mentioned?			

Travel	Yes	No	Details
22. Have you travelled abroad in the last 12 months ? Country / region / area — date returned *1*……..…….…..…. …… *2*…… …… *3*…… …… *4*…… …… **If "yes":** Were you unwell whilst traveling abroad or on your return to the UK? **23.** In the last twelve months have you had West Nile Virus? **24.** Have you ever had malaria or an unexplained fever associated with travel? **25.** Were you born or have you ever stayed for 6 months or more in a malarial area at any time? If yes, where and when? …… **26.** Were you or your mother born in Central/South America, or have you ever visited there for a continuous period of 4 weeks or more? **27.** Do you intend to travel abroad before your operation? If so where?			

Lifestyle questions

Just like blood donors we need to determine if bone donors are in a high risk group for HIV/AIDS. So some of the information we need may seem very personal, but this is necessary to comply with current regulations. So instead of asking direct questions I'm going to read the next section to you and at the end I'll ask if any of it applies to you.

YOU MUST NOT DONATE BONE IF YOU OR A SEXUAL PARTNER :

- are HIV positive
- have tested positive for hepatitis B, hepatitis C, or HTLV
- are a man who has had oral or anal sex with a man in the last 3 months, even using a condom
- have had sex with someone, in the last twelve months, who is HTLV positive
- have ever been given money or drugs for sex
- have ever injected yourself or been injected with illegal drugs, including body-building drugs
- have had sex with anyone who has been sexually active in parts of the world where AIDS/HIV is very common (this includes most countries in Africa)

Does any of the above apply to you? **Yes / No**

ALSO, YOU MUST NOT DONATE BONE IF YOU OR A SEXUAL PARTNER :

- have had acupuncture, a piercing, a tattoo or any cosmetic treatment that involved piercing your skin in the last 4 months

or:

- you, or a sexual partner are a haemophiliac who has received clotting factor concentrates

Does any of the above apply to you? **Yes / No**

Blood tests

Bone donors are tested to ensure they do not carry certain viruses. A small blood sample will be taken for this just before your operation. You will be notified of any test results which may affect your health, and you have the right to ask for all the results if you wish.

COVID -19

COVID-19 is an illness caused by infection with a newly identified Coronavirus. If you have suffered from COVID-19 we can only accept your donation if more than 28 days have elapsed between your recovery and your operation.

Also if you have been in contact with a confirmed or suspected case of COVID-19 we can accept your donation if more than 14 days have elapsed between the first date of contact and your operation and you have remained well.

We will therefore need to contact you after your operation to discuss the above.

If you would prefer to contact the Bone Bank after your operation, please call 01162 563016 (Mon – Fri 8.30am to 4.00pm)

For Bone Bank use only:

Comments:

Consenter's signature:

Date:

Consent I am willing to allow the surplus bone removed at my operation to be stored in the Leicester Bone & Tissue Bank for the purpose of transplantation and have been given the opportunity to ask questions. I agree to a sample of my blood being taken and stored at the time of surgery. This will be tested for infections including: • HIV I & II • Hepatitis B • Hepatitis C • HTLV (Human T-cell lymphotropic virus) • Syphilis I understand that I will be informed of any positive results which may affect my health, and have the right to ask for the results of all blood tests. I understand that if unsuitable for transplant my bone will be disposed of as clinical waste according to University Hospitals of Leicester NHS Trust clinical procedures. I understand that information relating to the donation will be stored in accordance with the Data Protection Act 2018 and may be discussed with my GP and other relevant health professionals. The information I have given is true to the best of my knowledge. I agree to a recording of this conversation being stored permanently by LBTB as a record of my informed consent to donate my bone.	**Yes**	**No**	**NA**

Comments

Donor's signature: …… Print name……..….

Date……..……

Consenter's signature…….…. Print name…….

Date……

LEICESTER BONE & TISSUE BANK

UHL NHS TRUST

GLENFIELD HOSPITAL

GROBY ROAD

LEICESTER LE3 9QP

Office: 0116 256 3016

Hospital Switchboard: 0300 303 1573

FRM4201/6 – Amnion Donor Medical / Lifestyle Telephone Risk Assessment

NHS Blood and Transplant

Effective date: 25/11/2020

Consent To Record	Yes	No
Do you agree to the conversation about donation between me (name of HCP) of NHSBT and you being recorded? May we use this recording and case detail for our records?		
For the purpose of this recording can you give me your full name, address and GP details **The recording will be stored as proof of the information that I give you and of the medical information and consent which you give to me.**		

First Name:	Surname:	Date of birth:
Hospital:	Date (of interview) :	Donation Number:

Donor medical history	Yes	No
1. What was/is the reason for your caesarean section?		
2. Was this pregnancy the result of IVF or fertility treatment? Please document source of eggs and sperm		
3. Are you aware of any abnormal tests on your baby?		
4. The next questions are random but are the questions which would normally **STOP** you from donating: i. Have you ever had a blood transfusion? (Where, When, What for?) ii. Have you ever been diagnosed with Cancer? iii. Or been investigated for cancer? iv. Have you ever had an organ or tissue transplant?		
5. Do you have any medical conditions requiring medication or regular check-ups?		
6. Give Details of **ALL** medications		
7. Have you suffered from any serious illnesses such as: • Chronic or Autoimmune Disease? • Hepatitis, Jaundice, liver Disease or Alcohol related Disease?		
8. Have you had any health problems related to exposure to toxic substances such as pesticides, lead, mercury, asbestos?		
9. Have you ever had any surgery or operations? (Spinal, Brain, which may have used dura mater? Where, When)		

Donor Name:	**DOB:**	**Yes**	**No**
10. Do you suffer from any other type of brain disease such as Alzheimer's, Parkinson's or Dementia? Or have you suffered from recent memory loss or confusion?			
11. To your knowledge has anyone in your family suffered with Creutzfeldt Jacob Disease (CJD)			
12. Have you ever received human pituitary extracts e.g.: growth Hormones or test injections for hormone imbalance?			
13. Have you come into contact with any infectious diseases in the last month? (Covid exposure)			
14. Have you had any immunisations or travel vaccines in the last 2 months? Have you come into contact with the smallpox vaccine in the last 2 months?			
15. In the last 3 months have you had any tattoos, body piercings, Botox injections, acupuncture, colonic irrigation, faecal transplantation or any other treatments or injuries involving piecing of the skin? (please document where/when)			
16. In the last 24 months have you been bitten or scratched by any animal (strays, pets, wild farm or ticks) a human Bats or been in close contact with bats? OR had Rabies			
17. Have you **EVER** been outside the UK? If No go to Q20			

Donor Name:	**DOB:**	**Yes**	**No**
18. Since this time last year have you been outside the UK? When did you return from your last trip? Country…….....Resort/City/region……When (month/year) _ _ / 2 0 _ _ Country…….....Resort/City/region……When (month/year) _ _ / 2 0 _ _ Please give as much travel information as possible.			
19. Do you intend to travel before your operation? Where? When? Country…….....Resort/City/region……When (month/year) _ _ / 2 0 _ _ Country…… Resort/City/Region……..When (month/year) _ _ / 2 0 _ _ Please give as much travel information as possible.			
20. Have you ever had malaria? Or Zika Virus?			
21. Have you had an unexplained fever, within 6 months of return of travel abroad			
22. Have you ever lived or stayed outside the UK for a continuous period of 6 months or more? Please state country/region and year			
23. Have you ever lived or worked in rural Central or South America or Mexico for a continuous period of 4 weeks or more?			
24. Were you or your mother born in central or south America or Mexico?			

Please use this space for any further medical information or any further comments

_____

_____

_____

_____

_____

_____

_____

Donor Name:	**DOB:**

Behavioural / Lifestyle History

YOU MUST NOT DONATE YOUR PLACENTA IF:

- You are HIV or HTLV positive or think you may be
- You know you carry the Hepatitis B or C virus
- If you have ever been diagnosed with Syphilis
- If you have had sex with someone who has had Viral Haemorrhagic fever

Do any of the above apply to you? **YES** **NO**

You must not donate your PLACENTA if in the last 12 MONTHS:

- You have injected yourself or been injected with habitual drugs of addiction
- Taken medication to prevent HIV infection e.g.: PrEP pre/post exposure prophylaxis

Have you ever had sex? **YES** **NO**
If YES:

- Have you been given payment for sex with money or drugs? Yes / No
- Ever had a sexually transmitted infection Yes / No

Have you had sex in the last 3 months? **YES** **NO**
If yes, have you had sex with:

- (for male patients) another man
- (For female patients) a man who has ever had sex with another man
- Anyone who is HTLV or HIV positive
- Anyone who has Hepatitis
- Anyone who has a sexually transmitted disease
- Anyone who has ever been given payment for sex with money or drugs
- Anyone in the last 12 months has injected or been injected with non-prescription drugs including performance enhancing drugs or injectable tanning agents
- Anyone who could have had sex in any parts of the world where AIDS/HIV is common (this includes most countries in Africa
- Anyone who has developed an illness related to travel such as ZIKA

Do any of the above apply to you? **YES** **NO**

Is there any other information you feel we need to know **YES** **NO**

Section D Medical history authorisation

Additional tests required **MAT** **T-CRUZI** **WNV** **N/A**

Is Medical History Acceptable? **Yes** **No** (If NO state reason)……

Is more information required? **Yes** **No** (if yes fill in communication form)

Refer to TES Medical staff / Clinical support Nurses? **Yes** **No** (if yes fill in FRM911)

Medical history taken by: …… Signature:……Date:……

Final Medical Authorisation

Additional Tests Required **MAT** **T_CRUZI** **WNV** **N/A**

Medical History **Pass** **Fail** (if fail state reason)……

Name……Signature ……..Date:……
Any further comments:

Cord Blood & Tissue Donor Screen

NHS Blood and Transplant

SECTION A ENROLMENT and CONSENT

MOTHER'S DETAILS:

Mother's name:.....

Mother's DOB:..... (must be 17yr or older)

Father's name:.....

Donor Hospital:.....

Affix donor mother's donation number barcode

GP name:.....

Address:.....

.....

Tel no.:.....

GENERAL QUESTIONNAIRE

1 I now need to ask you several questions, including some questions about risk behaviour. These questions are mainly about sexual contacts. We **have** to ask them, so I am going to read out a list of behaviours to you. If any apply, please tell me. If any questions are unclear and you would like me to repeat it or discuss it, please tell me at the end.

Have you ever:

a) Tested positive for HIV or HTLV, or if you think you may be HIV or HTLV positive?
b) Had hepatitis C, or think you may have hepatitis now?
c) Had hepatitis B, gonorrhoea or syphilis? If so, is there a possibility that you might not have been fully treated/have recovered?
d) Suffered from Crohn's disease or ulcerative colitis?
e) Received a transplant or graft of tissues or organs including those from non-human?
f) Been told you suffer from a genetic disease?
g) Had confirmed or possible viral haemorrhagic fever (e.g. Crimean-Congo Fever, Ebola, Lassa Fever Marburg Fever), Brucellosis or Q fever (Coxiella burnetii infection), worked as a stablehand, veterinarian, on a livestock farm or as an abattoir worker?
h) Been present in an area during an active outbreak of viral haemorrhagic fever, or been in contact (incl. sexual contact) with an individual infected with, or who was under investigation for viral haemorrhagic fever?
i) Been bitten by a non-human primate?

In the last 12 months have you:

j) Injected yourself or been injected with illegal recreational drugs, non-prescribed drugs, body building drugs or cosmetics?

In the last 3 months have you:

k) Had sex with anyone who is HIV positive, or sex with a partner who has been sexually active in areas where HIV is common (i.e. a partner who has been sexually active in Sub-Saharan Africa e.g. Swaziland, Botswana, Lesotho, South Africa)?
l) Had sex with anyone with Syphilis, hepatitis B, C or HTLV?
m) Had sex with anyone who has ever injected drugs including body building drugs?
n) Had sex with anyone who has ever been given money or drugs for sex?
o) Had a tattoo or piercing outside of the UK
p) Taken Pre-Exposure Prophylaxis (PrEP)/Truvada for prevention of HIV or have you taken or been prescribed Post-Exposure Prophylaxis (PEP) for prevention of HIV?
q) Been exposed to someone else's blood or body fluids through a needle prick, bite or broken skin?

During this pregnancy:

r) Have you received a "live" vaccine e.g. Rubella, MMR or yellow fever vaccine, or the oral typhoid vaccine?
s) Have you been in contact with someone vaccinated with smallpox?
t) Have you had chicken pox, shingles?
u) Have you had sex with a known haemophiliac or anyone with a bleeding disorder treated with blood derived coagulation factor concentrates?
v) Have you been diagnosed with herpes or have lesions or any wound that is infected or not healing?

Did You:

w) Have brain surgery or an operation for a tumour or cyst in your spine before August 1993?
x) Have malaria within the last 3 years?
y) Have cancer/malignancy (basal cell carcinoma and cancer in situ of cervix are acceptable)?
z) Have toxoplasmosis and recovered less than 18 months ago?
aa) Within the last **28** days; test positive for novel Coronavirus, have symptoms of COVID-19 such as fever, continuous cough, or shortness of breath, or a loss of, or change in, normal sense of taste or smell?
bb) Within the last **14** days; have you had contact with a person known or suspected to have a COVID-19 infection?
cc) Get bitten within the last 2 years, anywhere in the world by a bat or by any other mammal outside of the British Isles?

Do any of the above points apply to you?	**YES**	**NO**

SECTION B MEDICAL HISTORY

	YES	NO	Details
2 Is this or a previous pregnancy a result of IVF (in vitro fertilisation) or a surrogate pregnancy? If IVF; did the process involve injections?			*If yes – was the baby conceived using own **or** donated egg, sperm or embryo? Were gametes or embryo used fresh or after storage (for past IVF cycles or this pregnancy)? Where (country, hospital) and when (year) was IVF undertaken?*
3 Have you had any regular GP visits, hospital investigations, tests, medications or operations?			*If yes – give details including reasons/symptoms for investigations, diagnosis, date, treatment and outcome.*
4 Has any member of your baby's immediate family ever been diagnosed with, or investigated for cancer or leukaemia?			*If yes – give details, including relationship to the baby.*
5 Has anyone on either side of your baby's family* got thalassaemia, sickle cell anaemia, unusually shaped red blood cells or other blood disease/abnormality?			*If yes – give details, including relationship to the baby.*
6 Have you ever suffered from any autoimmune diseases such as: rheumatoid arthritis, systemic lupus erythematosus, multiple sclerosis or myasthenia gravis?			*If yes – give full details including dates, treatment, follow up.*
Risk of infection			
7 Have you ever received a blood transfusion? *Any transfusions in the perinatal period (esp. within 48 hours) of this delivery? (number of units, timing in relation to blood samples, donor's approx. weight)*			*If yes – give reason for transfusion and full details, including hospital, dates and country.*
8 In the last 4 months did you have acupuncture, tattooing, body piercing, cosmetic treatment that involves piercing the skin, an accidental needlestick injury or you have been exposed unintentionally to someone else's blood or body fluids?			*If yes – please give date (DD/MM/YY), was it performed within or outside the NHS/UK? Please provide details of the establishment. Obtain confirmation if single use needles were unwrapped in front of them.*
9 Have you had any injections for growth?			*If yes – give full details, including hospital, dates and country.*
10 Have you or anyone in your family been diagnosed with Creutzfeldt-Jacob disease or its variant?			*If yes – give details.*
11 In the last twelve months have you had sex with a man who has ever had sex with another man?			*If yes – please tell us approximately when this was.*

**Parents, grandparents, siblings and parents' siblings including egg, sperm or embryo donor.*

Travel Outside the UK			
12 Were you born or have you ever lived or stayed outside the UK for a continuous period of 6 months or more?			*If yes – give full details and dates.*
13 In the last 12 months have you travelled outside the UK? If yes, were you well there and after your return?			*If yes – give details of country visited and dates of travel and return; symptoms during travel and during the first month after return are particularly important.*
14 Were you or your mother born in Central America or South America?			*If yes – give full details and dates.*
15 Have you lived and/or worked in rural subsistence farming communities in Central or South America for a continuous period of four weeks or more?			*If yes – give details of relationship to the baby.*
16 Have you ever had malaria or an unexplained fever which you could have picked up while travelling?			*If yes–- give details, including relationship to the baby.*
17 Have you had any injections or vaccinations in the last 12 months?			*If yes – give details. If they had travel vacc. please enquire. Specifically, about whether they had oral typhoid vacc. As that is classed as "live".*
18 Were there any complications during delivery?			*If yes – give details.*
19 Did your baby require admission to the special care unit?			*If yes – give details; if antibiotics were given, was that to prevent or to treat infection?*
20 During this pregnancy have you had sexual contact with someone who has known to: have been diagnosed with Zika virus infection **or** travelled to **or** lived in a Zika affected area in the 6 months prior to the sexual contact?			
21 In the last five years have you injected yourself or been injected with illegal recreational drugs, non-prescribed drugs, body building drugs or cosmetics?			*If yes – please tell us approximately when this was, and what drug/cosmetic was involved.*
22 Finally, in the unlikely event of your baby or anyone in the immediate family goes on to develop a serious illness e.g. if you suspect or are confirmed to have COVID-19 within 14 days of this donation, we would appreciate if you could let us know using the contact details provided on your consent form.			

Interviewer

Name:..... Date:.....

Signature:..... Time:.....

BLOOD SAMPLES TAKEN (after delivery)

Please write number of samples that were obtained: **Purple** ☐ **White** ☐ **Red** ☐	
Check that labels used to label mother's blood samples are identical to labels used for consent pack paperwork.	Initial
Signature if different from interviewer: Date: Time:	
Novel Coronavirus/COVID-19 (SARS-COV-2) result check = Negative ☐ Positive ☐ Not done ☐ Sample Date ..... and Time ..... (obtain print out if possible)	Initial

Office use only:

SECTION C *(completed at NHSCBB Colindale Office)*

ADDITIONAL TESTS	PACK OUTCOME	
Malaria antibodies: Yes ☐ No ☐	Consent pack reviewed & accepted: Yes ☐ No ☐	Signature:
T Cruzi: Yes ☐ No ☐	Pack entered & linked on Hematos: Yes ☐ No ☐	.....
Other testing: e.g. West Nile Virus (WNV) Yes ☐ No ☐		Date: .....

SECTION D FOLLOW UP MEDICAL ASSESSMENT
(completed by a trained CBB staff member after delivery, usually by telephone)

Interviewer	*Confirmation of identity (check front page)*
Name:	Correct name of mother: Yes ☐ No ☐
Signature:	Correct date of birth of mother: Yes ☐ No ☐
Date:	Correct date of birth of baby: Yes ☐ No ☐

Details of follow-up:

Comments

Bone Marrow Donation

Welsh Bone Marrow Donor Registry (WBMDR)

Welsh Transplantation & Immunogenetics Laboratory, Welsh Blood Service, Pontyclun CF72 9WB, Wales, U.K.
Telephone: +44(0)1443 622177. Fax: +44(0)1443 622176. e-mail: wbmdr@wales.nhs.uk

WBM-430 20/10/2020

Donor Health History Screening Questionnaire

For use at: CT ☐ Work-up ☐ Other: _____

Donor Name: <@D_FULL_NAME@> **Donor ID: <@DONOR_NO@>**
Address: <@D_ADDR1@>, <@D_ADDR2@>
<@D_ADDR3@>
<@D_POSTCODE@> **GRID: <@D_GRID@>**
Date of Birth: <@D_DOB@> <@D_GRIDBAR@>

Please read questions carefully and answer to the best of your knowledge. If you need additional information, or clarification of the questions please contact the WBMDR on **FREEPHONE 0800 0187377**

Section 1: General Assessment and Donor Safety	**Make appropriate response**	**Staff**
1. Are you in good health?	Yes ☐ No ☐	
2. Do you have any infection now, or are you currently taking antibiotics? ***If yes***, please list (section 3):	Yes ☐ No ☐	
3. Are you currently taking any other medication including over-the-counter medications vitamins, herbal products, painkillers or aspirin)? ***If yes,*** please list (section 3), and identify the reason for their use, if known.	Yes ☐ No ☐	
4. Are you waiting to see a doctor, dentist, healthcare person or complementary therapist?	Yes ☐ No ☐	
5. **In the past 7 days**, have you had **any** dental treatment? ***If yes***, please provide details (section 3).	Yes ☐ No ☐	
6. Have you **ever** received an organ, bone marrow, stem cell or tissue transplant such as cornea or bone?	Yes ☐ No ☐	
7. Have you **ever** received a transfusion, from a source other than your own blood, including whole blood, packed red cells, plasma, or platelets?	Yes ☐ No ☐	29b
8. Have you **ever** been told that you should never give blood?	Yes ☐ No ☐	
9. Have you previously donated blood stem cells, (bone marrow or peripheral blood stem cells)? ***If yes***, please describe (section 3)	Yes ☐ No ☐	
10. Have you **ever** had surgery or been hospitalised for any reason? ***If yes***, please describe (section 3).	Yes ☐ No ☐	
11. **In the past 6 months**, have you had an endoscopy (magic eye)?	Yes ☐ No ☐	
12. Have you ever had problems with general or local anaesthesia? ***If yes***, please describe (section 3)	Yes ☐ No ☐	
13. Do you have any food, drug, latex or environmental allergies? ***If yes***, please list (section 3).	Yes ☐ No ☐	
14. Have you ever had neck, back, hip or spine problems? ***If yes***, please describe your current status, treatments and related surgery (section 3).	Yes ☐ No ☐	
15. Have you ever had breathing problems, including asthma, sleep apnoea or shortage of breath? ***If yes***, please explain (section 3).	Yes ☐ No ☐	
16. Have you **ever** had a stroke, heart disease, heart surgery, heart-related chest pains or rheumatic fever? ***If yes***, please provide details (section 3).	Yes ☐ No ☐	
17. Have you **ever** had cancer or epilepsy (fits)? ***If yes***, please provide details (section 3).	Yes ☐ No ☐	
18. Have either of your parents, or brothers, or sisters ever had leukaemia? ***If yes***, please provide details (section 3).	Yes ☐ No ☐	
19. **In the past 8 weeks**, have you had any immunisations, vaccinations or jabs (other than smallpox)? ***If yes***, please list (section 3).	Yes ☐ No ☐	
20. Are you planning to receive any immunisations, vaccinations or jabs? ***If yes***, please list what kind and when (section 3).	Yes ☐ No ☐	
21. **In the past 8 weeks** have you received a smallpox vaccination? If ***yes*** answer #21A. If ***no***; go to #22	Yes ☐ No ☐	3
21.a Did you have any illness due to the vaccination such as an eye infection?	Yes ☐ No ☐	3c

References: NMDP F00301 version 13.0

Donor ID : <@DONOR_NO@> GRID: <@D_GRID@> <@D_GRIDBAR@>

22. Have you had close contact with the vaccination site of anyone who has received the smallpox vaccine in the **past 3 months**? If ***yes*** answer #22A. If ***no***; go to #23	Yes ☐ No ☐	4
22.a Have you had any eye infection since the time of contact with the vaccination site?	Yes ☐ No ☐	4c
23. Is there any other past or present health information that you think we should be aware of? For example, any past surgery or serious medical conditions such as diabetes, fibromyalgia, blood clots or an autoimmune disorder? ***If yes***, please describe (section 3).	Yes ☐ No ☐	
Questions 24-26 for **FEMALE DONORS ONLY**	Male Donor NA ☐	
24. How many times have you been pregnant (inc. miscarriages)? No. of pregnancies _____ **(if zero, mark #25 NA; proceed to #26)**		
25. **In the past 9 months** have you been pregnant or are you pregnant now? NA ☐	Yes ☐ No ☐	
26. Do you plan to, become pregnant within the next 6 months?	Yes ☐ No ☐	

Section 2: Communicable and other Disease Assessment

	Make appropriate response	Staff
27. Do you have any auto-immune (e.g. rheumatoid arthritis) or inherited conditions? ***If yes***, please provide details (section 3).	Yes ☐ No ☐	
28. Have you **ever** had an unexplained fever whilst abroad or within 6 months of your return to the UK?). ***If yes***, please provide details (section 3).	Yes ☐ No ☐	
29. Have you **ever** stayed outside the UK (including business) for a continuous period of 6 months or more? ***If yes***, please provide details (section 3).	Yes ☐ No ☐	30
30. **In the past 12 months**, have you been outside the UK (including business). ***If yes***, please provide details (section 3).	Yes ☐ No ☐	30
31. **In the past 4 weeks**, have you been in contact with anyone with an infectious disease? ***If yes***, please provide details (section 3).	Yes ☐ No ☐	
32. Have you ever had (or tested positive for) a parasitic blood disease such as malaria, Chagas' disease or babesiosis? ***If yes***, please provide details (section 3).	Yes ☐ No ☐	10
33. Have you or any of your blood relatives been diagnosed with Creutzfeldt-Jakob disease (CJD)?	Yes ☐ No ☐	5
34. Have you been told that your family has an increased risk for Creutzfeldt-Jakob disease?	Yes ☐ No ☐	6
35. Do you have a degenerative neurological disease such as multiple sclerosis, Parkinson's or dementia?	Yes ☐ No ☐	7
36. **Since 1980**, have you received bovine (beef) insulin?	Yes ☐ No ☐	
37. Have you **ever** received growth hormone made from human pituitary glands?	Yes ☐ No ☐	9
38. Have you **ever** had a dura mater (or brain covering) transplant for a head or brain injury?	Yes ☐ No ☐	8
39. Are you HIV positive or do you think you may be HIV positive? Are you currently or have you ever been treated for HIV infection?	Yes ☐ No ☐	11
40. In the last 3 months have you taken pre-exposure or post- exposure prophylaxis (PreP or PEP) treatment for HIV?	Yes ☐ No ☐	
41. Do you have any of the following? • Unexplained weight loss, night sweats, or persistent diarrhoea • Unexplained persistent cough or shortness of breath • Unexplained persistent white spots or unusual sores in the mouth • Unexplained temperature higher than 38°C for more than 10 days • Blue or purple spots on or under the skin or mucous membranes • Lumps in the neck, armpits, or groin lasting longer than one month	Yes ☐ No ☐	12
42. Have you **ever** tested positive for HTLV (Human T-Lymphotrophic virus)? Or had sex with anyone with HTLV in the last 3 months	Yes ☐ No ☐	13
43. Have you **ever** tested positive for hepatitis or have you ever had yellow jaundice, liver disease, or hepatitis? ***If yes***, please provide details (section 3).	Yes ☐ No ☐	14

Donor ID : <@DONOR_NO@> GRID: <@D_GRID@> <@D_GRIDBAR@>

Section 2: Communicable and other Disease Assessment (cont.)

	Make appropriate response	Staff
44. Have you ever had a bleeding problem, such as haemophilia or other clotting factor deficiencies, and received human-derived clotting factor concentrates? ***If yes***, please provide details (section 3).	Yes ☐ No ☐	
45. Have you, any of your sexual partners, or any members of your household ever had a xenotransplant or medical procedure that involved being exposed to live cells, tissues or organs from an animal? ***If yes***, please provide details (section 3).	Yes ☐ No ☐	16
46. FEMALE DONORS ONLY: In the **past 12 months,** have you had sex with a male who has had sex, even once, with another male in the past 5 years? ***If No*** mark #45a as NA ***If yes*** please answer question #45a	Yes ☐ No ☐ Male Donor NA ☐	25
46.a **In the past 12 months** have you had sex with a male who has had sex, even once, with another male in the past 12 months? NA ☐	Yes ☐ No ☐	25
47. MALE DONORS ONLY: **In the past 5 years**, have you had sex, even once, with another male? ***If No*** mark #46a as NA ***If yes*** please answer question #46a	Yes ☐ No ☐ Female Donor NA ☐	26
47.a **In the past 12 months** have you had sex, even once, with another male? NA ☐	Yes ☐ No ☐	26
48. **In the past 4 months,** have you had acupuncture? ***If yes***, please provide (section 3), information on whether Acupuncturist was registered with a statutory registry body	Yes ☐ No ☐	
49. **In the past 12 months,** have you had a tattoo? ***If yes***, please provide (section 3), information about tattoo application and whether performed in licensed establishment	Yes ☐ No ☐	17
50. **In the past 12 months,** have you had ear, skin or body piercing?	Yes ☐ No ☐	18
51. **In the past 12 months,** have you had an accidental needle stick or have you come into contact with someone else's blood through an open wound, non-intact skin, or mucous membrane (for example, into your eye, mouth etc.)?	Yes ☐ No ☐	19
52. **In the past 12 months,** have you lived with or had sexual contact with anyone having yellow jaundice or hepatitis?	Yes ☐ No ☐	20
53. **In the past 12 months,** have you had a confirmed positive test or been treated for syphilis or gonorrhoea?	Yes ☐ No ☐	15
54. **In the past 12 months,** have you had had sex, even once, with anyone who has used a needle for illegal or non-prescription drugs?	Yes ☐ No ☐	21
55. **In the past 12 months,** have you had sex, even once, with anyone who has taken money or drugs for sex?	Yes ☐ No ☐	22
56. **In the past 12 months,** have you had sex, even once, with anyone who has taken human derived clotting factors?	Yes ☐ No ☐	
57. **In the past 12 months,** have you had sex, even once, with anyone who has AIDS or has ever tested positive for the AIDS virus?	Yes ☐ No ☐	23
58. **In the past 12 months,** have you been held in a jail, prison or young offenders institution for more than 72 continuous hours?	Yes ☐ No ☐	24
59. Have you **ever** used a needle, even once, to take any illegal or non-prescription drugs, including body building drugs?	Yes ☐ No ☐	28
60. Have you **ever** been given money or drugs in exchange for sex?	Yes ☐ No ☐	27
61. **Since 1977**, were you born in or have you lived in Africa? ***If No*** mark #61a & #61b as NA; proceed to #62 ***If yes*** answer questions #61a & #61b	Yes ☐ No ☐	
61.a Was it Benin, Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Kenya, Niger or Nigeria, Senegal, Togo or Zambia? NA ☐	Yes ☐ No ☐	
61.b Did you receive a blood transfusion or medical treatment with a blood product while there? NA ☐	Yes ☐ No ☐	

Donor ID : <@DONOR_NO@> GRID: <@D_GRID@> <@D_GRIDBAR@>

Section 2: Communicable and other Disease Assessment (cont.)

	Make appropriate response	Staff
62. Have you had sex with anyone who may **ever** have had sex in parts of the world where AIDS/HIV is very common (this includes most countries in Africa)?	Yes ☐ No ☐	
63. Have you had sex with anyone who, since 1977, was born or lived in Africa? ***If No*** mark #62a as NA; proceed to #63. ***If yes*** answer question #62a	Yes ☐ No ☐	
63.a Was the person born in or did they live in Benin, Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Kenya, Niger or Nigeria, Senegal, Togo or Zambia? NA ☐	Yes ☐ No ☐	
64. Were you or your mother born in Central or South America?	Yes ☐ No ☐	
65. Have you **ever** lived in, or visited, or had a blood transfusion in Central or South America?	Yes ☐ No ☐	
66. **In the past 6 months,** have you travelled to or resided in a risk area for the Zika virus?	Yes ☐ No ☐	31
67. **In the past 6 months,** have you been diagnosed with the Zika virus? ***If yes***, please provide (section 3), date of diagnosis.	Yes ☐ No ☐	32
68. **In the past 6 months,** have you had sexual contact with a person who is known to have been diagnosed with the Zika virus in the past 6 months prior to the sexual contact?	Yes ☐ No ☐	33
69. **In the past 6 months,** have you had sexual contact with a person who is known to have travelled to or resided in a risk area for the Zika virus in the past 6 months prior to the sexual contact?	Yes ☐ No ☐	34
70. Have you **ever** been significantly exposed to, or ingested a poisonous substance, for example; cyanide, lead, mercury or gold? ***If yes***, please provide, in section 3, details of what the poisonous substance was, and when and for how long were you exposed.	Yes ☐ No ☐	
71. Have you been in contact with anyone who has returned from a novel Coronavirus risk area or has been affected by Coronavirus within the last 28 days?	Yes ☐ No ☐	
72. In the **past 28 days** have you travelled to China or an area affected by Novel Coronavirus	Yes ☐ No ☐	
73. In the **past 3 months** have you been tested positive for Novel Coronavirus	Yes ☐ No ☐	

Section 3: Donor Notes – (please record question number followed by any additional information)

Bone Marrow Donation

Welsh Bone Marrow Donor Registry (WBMDR)

Welsh Transplantation & Immunogenetics Laboratory, Welsh Blood Service, Pontyclun CF72 9WB, Wales, U.K.
Telephone: +44(0)1443 622177. Fax: +44(0)1443 622176. e-mail: wbmdr@wales.nhs.uk

Section 4: For WBMDR use only

Donor ID : <@DONOR_NO@> GRID: <@D_GRID@> <@D_GRIDBAR@>

Section 5: Donor Consent and authorisation – Please read carefully

I have read the document entitled 'Donating Your Blood Stem Cells' - **WBM-300** (02/11), or if at workup documents 'Donating peripheral blood stem cells' **WBM-411a** (02/11) and 'Donating bone marrow' **WBM-411b** (02/11) and have been given the opportunity to ask questions about the information requested on this questionnaire.

I confirm that to the best of my knowledge the information supplied by me is true.

I agree to blood tests to exclude evidence of important infections. These are those caused by the AIDS virus (HIV), Hepatitis B, Hepatitis C, Syphilis and Human T-cell Lymphotrophic Virus (HTLV, a potential cause of leukaemia and nerve damage). I understand that I will be informed of any positive results from these tests and provided with any necessary advice regarding implications for my own health.

I also agree to be tested to see if I have been previously infected with Cytomegalovirus (CMV, a common infection), Epstein - Barr virus (EBV, the virus that causes glandular fever), Hepatitis E Virus (HEV a virus contracted from undercooked meat and shellfish) and Toxoplasmosis (an infection commonly caught from cats); these can cause severe illness in people who have had a transplant. I will not normally be told the results of these tests. This is because they are common infections and many people will have positive test results. I can however request to be informed of the results. If testing for other infections is considered important for the person receiving my cells, these will not be performed without additional consent.

I authorise the release of the information on this questionnaire to the WBMDR and its agents and representatives and other medical facilities known as transplant centres. This release may only be in connection with the possibility of the donation of my cells to a patient.

I consent to the Welsh Blood Service processing this personal data in accordance with the provisions of the Data Protection Legislation. Any relevant correspondence about your medical history is also kept. The WBS complies at all times with the General Medical Council (GMC) guidelines on the use of medical information held about you.
If you wish to find out more about our commitment to protecting the confidentiality of your data, please ask for the "Your Information - Your Rights as a Donor" leaflet.

I understand that:

- The requested information is important because if I am at risk of infection or other diseases, my donated cells may transmit these diseases.
- Any information identifying me will remain confidential.
- The potential recipient of my donation may be advised of any disease risks.
- Authorising the release of this information is voluntary and that I can refuse to sign this document.

By signing I acknowledge that I have read, understood and agreed with the above.

DONOR NAME (please print) _____

Donor Signature _____ Date: _____

Section 6: To be completed by Donor Centre Staff / Independent Medical examiner

This form was completed

☐ Through oral interview performed by Donor Centre Staff / Medical Physician

Name _____ (Donor Centre staff / Independent medical examiner) _____ (Date of interview)

☐ Self administered by donor and reviewed by Donor Centre staff

Name _____ (Donor Centre staff) _____ (Date Reviewed)

References: NMDP F00301 version 13.0

Welsh Bone Marrow Donor Registry (WBMDR)

Welsh Transplantation & Immunogenetics Laboratory, Welsh Blood Service, Pontyclun CF72 9WB, Wales, U.K.
Telephone: +44(0)1443 622177. Fax: +44(0)1443 622176. e-mail: wbmdr@wales.nhs.uk

Referred to: WBMDR Nurse on date: ……. Comments: (use section 4 if necessary) Completed by: …….. Date ……	Referred to: WBS Medical Officer on date: ……. Comments: (use section 4 if necessary) Completed by: …… Date ……

National Marrow Donor Program®

RISK ASSESSMENT - INTERNATIONAL DONOR

Recipient Identification Number: _____

GRID: _____

NMDP or Cooperative Registry Donor ID: _____

Questions regarding the completion of this document should be directed to NMDP Case Management.

General Instructions

- Submit this document for all International Adult Donors providing stem cells through the NMDP.
- Complete all three sections of this document.
  NOTE: Sections may be completed by different staff and on different dates, if needed.
- Ensure all information is current to within six months of the confirmed collection date.

Risk Assessment Overview

- All donors providing stem cells through the NMDP must be evaluated for the risk of exposure to or evidence of relevant communicable diseases and xenotransplantation.
- Relevant communicable diseases include: HIV-1/2, Hepatitis B and C, HTLV I/II, West Nile virus, Syphilis, Vaccinia virus, Creutzfeldt - Jakob disease, Variant Creutzfeldt - Jakob disease, Chagas, Sepsis, and Zika virus.
- Along with infectious disease testing, the possible risk of exposure to or evidence of these infections is assessed by 1) health history screening questions, 2) review of other relevant medical records, and 3) physical examination.
- This document is divided into three sections to record the outcome of these three assessment steps.
- Information may be shared with the Transplant Center if a risk of exposure to or evidence of a relevant communicable disease is identified.

SECTION 1: Health History Screening

Directions:

1. The questions do not need to be asked exactly as worded by the NMDP but they must maintain the intended content of the question, after translation into the appropriate language.
2. For each required question, mark "yes" or "no" or "not asked" (if a specific question was not asked due to local regulations) or "not answered" (if a donor chose not to answer a specific question). Explain "yes" responses in the Comments Section on page 4. For questions 17 through 28 (on page 3), provide an event or last contact date whenever possible.
   NOTE: Some sub-questions are not required to be asked and may remain blank if the lead question's answer is "no". Follow instructions within the document for these questions.
3. Enter name and date at the end of Section 1 on page 4.

European countries assessed in #29 include:

Albania, Austria, Belgium, Bosnia-Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland (Republic of), Italy, Liechtenstein, Luxembourg, Macedonia, Netherlands (Holland), Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, UK, and Federal Republic of Yugoslavia (Kosovo, Montenegro, and Serbia).

Date the donor provided answers used for completion of Section 1: _____

Date (MM /DD/YY)

NMDP or Cooperative Registry Donor ID: _____ GRID _____

1. In the past 120 days (4 months), have you had a positive test for West Nile Virus?	Yes	No	Not Asked Not Answered	
2. Have you ever been told by a healthcare professional that you had or might have had West Nile Virus? If *YES*, answer #2A. If *NO*, do not answer #2A; go to #3.	Yes	No	Not Asked Not Answered	
2A. When were you told this? *(Date)*				
3. In the past 8 weeks, have you received a smallpox vaccination? If *YES*, answer #3A – #3C. If *NO*, do not answer #3A – #3C; go to #4.	Yes	No	Not Asked Not Answered	
3A. When did you receive the vaccination? *(Date)*				
3B. Has the vaccination scab fallen off your skin by itself?	Yes	No	Not Asked Not Answered	
3C. Did you have any illness or complications due to the vaccination such as an eye infection or a rash, an allergic reaction, sores away from the vaccination site?	Yes	No	Not Asked Not Answered	
4. Have you had close contact with the vaccination site of anyone who has received the smallpox vaccine in the past 3 months? If *YES*, answer #4A - #4C. If *NO*, do not answer #4A - #4C; go to #5.	Yes	No	Not Asked Not Answered	
4A. When did the person receive the vaccination? *(Date)*				
4B. When was the contact? *(Date)*				
4C. Have <u>you</u> had any new skin rash or sores or an eye infection since the time of contact?	Yes	No	Not Asked Not Answered	
5. Have you been diagnosed with Creutzfeldt - Jakob disease (CJD) or variant CJD?	Yes	No	Not Asked Not Answered	
6. Have any of your blood relatives been diagnosed with Creutzfeldt - Jakob disease or have you been told that your family has an increased risk for this disease?	Yes	No	Not Asked Not Answered	
7. Do you have a degenerative neurological condition such as dementia or any other disease of the central nervous system where the cause is unknown?	Yes	No	Not Asked Not Answered	
8. Have you ever had a dura mater (or brain covering) transplant for a head or brain injury?	Yes	No	Not Asked Not Answered	
9. Have you ever received growth hormone made from human pituitary glands?	Yes	No	Not Asked Not Answered	
10. Have you ever had Chagas disease or any positive tests for Chagas, *including screening tests*?	Yes	No	Not Asked Not Answered	
11. Do you have HIV or AIDS or have you ever tested positive for the HIV virus, *including screening tests*?	Yes	No	Not Asked Not Answered	
12. Do you have any of the following? • <u>unexplained</u> weight loss, night sweats, or persistent diarrhea • <u>unexplained</u> persistent cough or shortness of breath • <u>unexplained</u> persistent white spots or unusual sores in the mouth • <u>unexplained</u> temperature higher than 100.5°F (38.0°C) for more than ten days • blue or purple spots on or under the skin or mucous membranes • lumps in the neck, armpits, or groin lasting longer than one month Note: These are symptoms of a <u>possible</u> infection with HIV. It is recognized that these symptoms can be present in many other common medical conditions, making evaluation complex. If a donor has one or more of the listed symptoms, not contributable to a logical underlying cause, the donor must be thoroughly evaluated for this symptom during the physical exam.	Yes	No	Not Asked Not Answered	
13. Have you ever tested positive for HTLV (Human T-lymphotropic virus), *including screening tests*?	Yes	No	Not Asked Not Answered	
14. Have you ever tested positive for hepatitis, *including screening tests,* or have you ever had yellow jaundice, liver disease, or hepatitis since the age of 11 years?	Yes	No	Not Asked Not Answered	
15. Have you ever tested positive for syphilis, *including screening tests*, or ever been treated for syphilis?	Yes	No	Not Asked Not Answered	
16. Have you, any of your sexual partners, or any members of your household ever had a xenotransplant or a medical procedure that involved being exposed to live cells, tissues, or organs from an animal?	Yes	No	Not Asked Not Answered	

NMDP or Cooperative Registry Donor ID: _____ GRID _____

17. In the past 12 months, have you had a tattoo? Provide date of tattoo application and if you have any signs of infection. Note if performed in licensed establishment.	Yes	No	Not Asked Not Answered
18. In the past 12 months, have you had an ear, skin, or body piercing using shared instruments or needles? (NOTE: Sterile and/or single use instruments such as a "piercing gun" from a licensed establishment are not considered "shared instruments.")	Yes	No	Not Asked Not Answered
19. In the past 12 months, have you had an accidental needle stick or have you come into contact with someone else's blood through an open wound, non-intact skin (for example, a cut or sore), or mucous membrane (for example, into your eye or mouth)?	Yes	No	Not Asked Not Answered
20. In the past 12 months, have you lived with or had sexual contact with anyone having yellow jaundice, hepatitis, or have you received Hepatitis B Immune Globulin (HBIG)?	Yes	No	Not Asked Not Answered
21. In the past 12 months, have you had sex, even once, with anyone who has used a needle to take drugs, steroids, or anything else not prescribed by a doctor in the past 5 years?	Yes	No	Not Asked Not Answered
22. In the past 12 months, have you given money, drugs, or other payment for sex OR have you had sex, even once, with anyone who has taken money, drugs or other payment in exchange for sex in the past 5 years?	Yes	No	Not Asked Not Answered
23. In the past 12 months, have you had sex, even once, with anyone who has HIV or AIDS or tested positive for the HIV virus?	Yes	No	Not Asked Not Answered
24. In the past 12 months, have you been held in a jail, prison, juvenile detention, or lockup for more than 72 continuous hours?	Yes	No	Not Asked Not Answered

If the donor is FEMALE, answer #25. (Do not answer #26.) If the donor is MALE, answer #26. (Do not answer #25.)

25. FEMALE DONOR: In the past 12 months, have you had sex with a male who has had sex, even once, with another male in the past 5 years?	Yes	No	Not Asked Not Answered
26. MALE DONOR: In the past 5 years, have you had sex, even once, with another male?	Yes	No	Not Asked Not Answered
27. In the past 5 years, have you taken money, drugs, or other payment in exchange for sex?	Yes	No	Not Asked Not Answered
28. In the past 5 years, have you used a needle, even once, to take drugs, steroids, or anything else not prescribed by a doctor?	Yes	No	Not Asked Not Answered
29. Since 1980 to present, have you ever lived in or traveled to countries in Europe? (See reference list.) If *YES*, answer #29A - #29C. If *NO*, do not answer #29A - #29C; go to #30.	Yes	No	Not Asked Not Answered
29A. From 1980 through 1996, did you spend time that adds up to 3 months or more in the United Kingdom (England, Northern Ireland, Scotland, Wales, the Isle of Man, the Channel Islands, Gibraltar, or the Falkland Islands)? If born after 1996, mark *No*.	Yes	No ☐	Not Asked Not Answered
29B. Since 1980, did you receive a transfusion of blood or blood components while in the UK or France?	Yes	No ☐	Not Asked Not Answered
29C. Since 1980, have you spent time that adds up to 5 years or more in Europe (include any time that you may have spent in the UK from 1980 through 1996)?	Yes	No ☐	Not Asked Not Answered
30. From 1980 through 1996, were you a member of the U.S. military or their dependent or a civilian military employee or their dependent? If born after 1996, mark *No*. If *YES,* answer #30A & #30B. If *NO,* do not answer #30A & #30B.	Yes ☐	No ☐	Not Asked Not Answered
30A. Did you spend a total of 6 months or more between 1980 and 1990 at a military base in Belgium, The Netherlands or Germany?	Yes	No	Not Asked Not Answered
30B. Did you spend a total of 6 months or more between 1980 and 1996 at a military base in Spain, Portugal, Turkey, Italy or Greece?	Yes	No	Not Asked Not Answered

NMDP or Cooperative Registry Donor ID: _____ GRID _____

Directions for 33 and 34:

- For 33: If the donor does not know the answer to 33, ask if they are able to obtain the information from the sexual partner.
- For 34: If the donor does not know the answer to 34, ask if they are able to obtain a list of the countries the sexual partner traveled to or resided in for the six months before the last sexual contact.

31. *In the past 6 months* have you traveled to or resided in a **risk area*** for the Zika virus?	Yes	No	Not Asked Not Answered
32. *In the past 6 months* have you been diagnosed with the Zika virus infection? If Yes, date of diagnosis:	Yes	No	Not Asked Not Answered
In the past 12 months have you had sexual contact with a person who: 33. was diagnosed with the Zika virus infection? (For Yes response, provide date of diagnosis in Comments.)	Yes	No	Not Asked Not Answered Unknown
34. traveled to or resided in a **risk area*** for the Zika virus? (For Yes response, provide sexual partner's travel date and last sexual contact in Comments.)	Yes	No	Not Asked Not Answered Unknown

*RISK AREA: Review both the following webpages for the most current information on identifying Zika risk areas:
- *U.S. Center for Disease Control's Active Zika Virus Transmission Map* webpage (https://wwwnc.cdc.gov/travel/page/zika-travel-information)
- *NMDP's Zika Risk Areas within the U.S.* webpage (https://network.bethematchclinical.org/workarea/downloadasset.aspx?id=14882)

Comments:

Section 1 Completed By

Printed Name Date (MM/DD/YY)

NMDP or Cooperative Registry Donor ID: _____ GRID _____

SECTION 2: Review of Other Relevant Medical Records

Directions:

1. The NMDP requires that a review of medical records be completed, due to our government's regulations. This review would include any records for the donor that are readily available to you or can be obtained within a reasonable amount of time (as determined by your center) that would not compromise the collection/transplant schedule. Examples of these donor records may include some, all or any of the following:
    - Any non-NMDP tested IDMs which includes any IDM testing performed by your center's lab (before and/or at the Workup stage).
    - Any non-NMDP assessments which include any questionnaires, exams or assessments that are particular to your center (before and/or at the Workup stage including evaluation for previous donations).
    - Any hospitalization or medical treatment records of your donor, if applicable and that are readily available to you.

2. Mark the applicable box (A-C) to indicate relevant medical record review findings; enter name and date at the end of Section 2.

    A. No risk of exposure to or evidence of a relevant communicable disease was identified by review of medical records.

    B. A review of relevant medical records was not performed.

    C. A risk of exposure to or evidence of a relevant communicable disease was identified by review of medical records. Describe findings below; include type of medical record and dates, as applicable. ↓

Comments:

Section 2 Completed By

_____

Printed Name Date (MM/DD/YY)

NMDP or Cooperative Registry Donor ID: _____ GRID _____

SECTION 3: Review of Physical Exam

Directions:

1. A review of the physical exam (PE) results should be performed to confirm that no risk or evidence of relevant communicable diseases as listed in the table below was identified by the examining medical professional.
2. Mark the applicable box (A-C) to indicate the outcome of the review of the physical exam; enter name and date at the end of Section 3.

A. No risk or physical evidence listed below was identified on exam.

B. A physical exam was not performed.

C. A risk or physical evidence listed below was identified on exam.

↓ Mark all applicable categories (#1 - #13); describe details in comments section below.

1. ☐ Nonmedical percutaneous drug use such as needle tracks including examination of tattoos, which may be covering needle tracks
2. ☐ Tattooing performed *in preceding 12 months*
   If present, note date(s) of tattooing: _____
3. ☐ Ear or body piercing performed *in preceding 12 months* using shared instruments or needles
   If present, note date(s) of piercing: _____
4. ☐ West Nile Virus such as fever, headache, body aches, eye pain, lymphadenopathy, neck stiffness, skin rash on the trunk, stupor, disorientation, tremors, convulsions, and muscle weakness or paralysis
5. ☐ HIV-1/2 such as disseminated lymphadenopathy, blue or purple spots consistent with Kaposi's sarcoma, or unexplained oral thrush
6. ☐ Hepatitis B and C such as unexplained jaundice, hepatomegaly, or icterus
7. ☐ Vaccinia virus infection such as generalized vesicular rash (generalized vaccinia), large scab consistent with recent smallpox immunization, severely necrotic lesions consistent with vaccinia necrosum, eczema vaccinatum, or corneal scarring consistent with vaccinal keratitis
8. ☐ HTLV I/II such as unexplained paraparesis
9. ☐ Chagas such as fever, lymphadenopathy, myocarditis/cardiomyopathy, or hepatosplenomegaly
10. ☐ Creutzfeldt-Jakob disease (CJD) or variant CJD such as dementia
11. ☐ Sepsis or systemic infection such as unexplained generalized rash or fever
12. ☐ Syphilis such as palmar rash, fever or other constitutional symptoms
13. ☐ Zika such as fever, rash, headache, joint pain, conjunctivitis, or muscle pain
14. ☐ Sexually transmitted diseases such as ulcerative disease, herpes simplex, chancroid, or chondyloma in genital or anal areas (*NOTE:* Only potential donors reporting high risk behavior for sexually transmitted infections [e.g. HIV] must be examined with a genitourinary focus for any physical evidence of infection.)

Comments:

Section 3 completed by

_____

Printed Name Date (MM/DD/YY)

Travel History

1	Have you **ever** had malaria, or suffered an unexplained fever during or after visiting a malaria risk area? If yes, when/where ……	Yes ☐ Test malaria anti-bodies. Inform TC	No ☐
2	Have you lived in a malaria risk area for six or more continuous months at any time of your life? If yes, when/where ……	Yes ☐ Test malaria anti-bodies. Inform TC	No ☐
3	Have you travelled outside the UK and Ireland **in the last 12 months**? Please give all destinations with month and year of travel below …… …… …… …… …… …… …… …… …… **NOTES FOR ASSESSING CLINICIAN** For endemic areas and high-risk season for each country visited refer to geographical disease risk index (www.transfusionguidelines.org). If testing is required but results cannot be obtained in time donor can proceed at TC's discretion. **Malaria** All visitors to endemic areas within the last 12 months should be tested, regardless of prophylaxis **West Nile Virus** Accept without testing: *- Visitors to endemic areas outside of high-risk season* *- Visitors to endemic areas during high risk season who returned to the UK over 28 days ago and had neither symptoms nor evidence of WNV infection while abroad or since return* WNV NAT should be tested in the following instances: *- Visitors to endemic areas during high risk season (See Geographical Disease Risk Index) who have returned to the UK in last 28 days* *- Visitors to endemic areas during high risk season (See Geographical Disease Risk Index) who have returned to the UK within last six months and had symptoms suggestive of WNV while abroad or within 28 days of return* **Tropical Viruses - Dengue Virus, Chikungunya, Zika Virus (see Q6 also)** Accept without testing: *- Visitors to endemic areas who have returned to the UK over 28 days ago and had neither symptoms nor evidence suggestive of Chikungunya, Dengue or Zika virus infection while abroad or since return* NAT should be tested in the following instances: *- Visitors to endemic areas who have returned to the UK in last 28 days* *- Visitors to endemic areas who have returned to the UK within last six months and had symptoms or evidence of Dengue, Chikungunya or Zika virus infection while abroad or within 28 days of return* **T. Cruzi (American Trypanosomiasis / Chagas' Disease** See Qs 7-9	Yes ☐	No ☐
4	Do you have plans to travel outside the UK and Ireland **between now and your donation date**? **If yes, where and when?** ……	Yes ☐ Consult Geographical Disease Risk Index	No ☐
5	Have you **ever** been diagnosed with West Nile Virus? If yes, when ……	Yes ☐ Test WNV NAT if within last four months. Inform TC	No ☐
	Zika Virus Q6 - Please notify Anthony Nolan if donor answers yes to these questions. Additional testing not required.		

6	Have you had sex with a male partner who had travelled or lived in a Zika virus affected area during the 3 months previous to sex? (*If you are unsure about regions affected by Zika Virus please discuss with the doctor / nurse during your medical assessment)* If yes, was the date of sex within the last 28 days?	Yes ☐ Yes ☐	No ☐ No ☐
	T. Cruzi (American Trypanosomiasis / Chagas' Disease) Qs7-9 All donors answering yes to any of these questions must have a T Cruzi antibody test performed. Donors who have travelled to these areas who do not answer yes to these questions do not need to be tested		
7	Have you **ever** been diagnosed with South American Trypanosomiasis (Chagas) disease? If yes, please provide details ……	Yes ☐	No ☐
8	Were you or your mother born in South America or Central America (including Mexico, excluding Cuba)? If yes, please provide details ……	Yes ☐	No ☐
9	Have you lived and/or worked in rural farming communities in South America or Central America (including Mexico, excluding Cuba) for a continuous period of four weeks or more? If yes, please provide details ……	Yes ☐	No ☐

Medical History			
10a	Have you ever been diagnosed with Viral Haemorrhagic Fever (VHF), including Crimean-Congo Fever, Ebola, Lassa Fever, Marburg fever? If yes, please provide details ……	Yes ☐ Defer	No ☐
b.	Have you ever travelled to a VHF endemic area? e.g. Guinea, Liberia, Sierra Leone, Nigeria, etc. If yes, please provide details ……	Yes ☐ Defer if in area during active outbreak, if not defer for six months post return	No ☐
c.	Have you ever had a sexual partner diagnosed with VHF at any time before your last sexual contact? If yes, please provide details ……	Yes ☐ Defer if partner diagnosed before last contact	No ☐
11	Have you **ever** been diagnosed with Creutzfeld-Jakob-Disease (CJD) or do you have a degenerative neurological disease? If yes, please provide details ……	Yes ☐ Defer	No ☐
12	Has anyone in your family had CJD, or have you been told that your family has an increased risk for CJD? If yes, please provide details ……	Yes ☐ Inform TC	No ☐
13	Have you had brain surgery or an operation for a tumour or cyst on the spine **prior** to August 1992? If yes, please provide details ……	Yes ☐ Inform TC	No ☐
14	**Have you ever** been treated with human pituitary extracts such as growth hormones prior to 1985? If yes, please provide details ……	Yes ☐ Inform TC	No ☐
15a	Have you ever suffered a head injury? **If no go to Q16**.	Yes ☐	No ☐

15a cont	If yes please provide details of when and what type ……		
b.	Have you suffered from more than 3 concussions in your lifetime? If yes were there more than 6? ……	Yes ☐	No ☐
c.	Did you lose conscious for than 5 minutes? If yes, was it more than 1 hour?.....	Yes ☐	No ☐
d.	Post injury have you suffered from any of the following symptoms that lasted more than 72 hours: **short term memory loss, blurred vision, light or noise sensitivity, nausea or vomiting, dizziness or balance problems, difficulty thinking, poor concentration, seizure, personality changes, severe headache** If yes please provide more details……	Yes ☐	No ☐
16	Have you **ever** received a corneal transplant, or had any other operations on your eyes? If yes, please provide details ……	Yes ☐ Obtain details re use of scleral/other ocular tissue grafts	No ☐
17	Have you **ever** received a xenograft transplant (a surgical graft of tissue from one species to an unlike species)? If yes, please provide details ……	Yes ☐ Defer	No ☐
18	Have you **ever** been bitten by a non-human primate? e.g. ape, lemur If yes, please provide details ……	Yes ☐ Defer	No ☐
19	Have you been bitten by a bat in the last two years? If yes, please provide details ……	Yes ☐ Defer for two years from date of bite	No ☐
20	Have you ever been exposed to rabies? If yes, please provide details …… If yes, were you cleared by a Doctor/Physician? ……	Yes ☐ Defer for two years from date of exposure, if were medically cleared.	No ☐
21	Are you HIV positive, have you **ever** tested positive for HIV or do you think you may be HIV positive? If yes, please provide details ……	Yes ☐ Defer	No ☐
22	Have you **ever** had hepatitis B or C, have you **ever** tested positive for hepatitis B or C, or do you think you may have hepatitis now? If yes, please provide details ……	Yes ☐ Defer	No ☐
23	Have you **ever** had yellow jaundice, liver disease or hepatitis (except for jaundice as a young baby)? If yes, please provide details ……	Yes ☐ Inform TC	No ☐
24	Have you **ever** had a bleeding problem, such as haemophilia or other clotting factor deficiencies and received blood products/clotting factor concentrates?	Yes ☐ Defer	No ☐

	If yes, please provide details ……		
25	Within the last **four months** have you had an injury which could have put you at risk of hepatitis or HIV – for example a needle stick injury, coming into contact with someone else's blood through an open wound, non-intact skin, or mucous membrane (e.g. into your eye or mouth) If yes, please provide details …… ……	Yes ☐ Inform TC	No ☐
26	Have you **ever** tested positive for HTLV (Human T-lymphotropic virus)? If yes, when ……	Yes ☐ Inform TC	No ☐
27	**In the past 12 months** have you had a confirmed positive test result or been treated for syphilis or gonorrhoea? If yes, when ……	Yes ☐ Inform TC	No ☐
28	Have you received a transfusion of blood, platelets or other blood product **since 1980**? If yes, when and where……	Yes ☐ Inform TC	No ☐
29	Has any **first degree** relative (parent, sibling, child) been diagnosed with a blood cancer or any other blood disorder? If yes, please provide details …… ……	Yes ☐ Inform TC	No ☐
30	Are you a blood donor? If yes, when was the last time you donated blood?……	Yes ☐	No ☐
31	Have you had any immunisations / vaccinations in the last **four weeks**? Do you have plans to receive any before your donation? If yes, what/when?.....	Yes ☐ Check vaccination type (e.g. live, etc…). Inform TC, if live defer	No ☐
32	Do you have any allergies? If yes, please list …… …… …… ……	Yes ☐ Inform TC if relevant	No ☐

Lifestyle			
33	**Have you ever** taken or been exposed to or ingested cyanide, lead or mercury? **Have you ever** ingested gold? If yes, please provide details …… …… ……	Yes ☐	No ☐
34	Have you taken **PrEP** (Pre-Exposure Prophylaxis, anti-HIV medication) at any point in the last **three months**?	Yes ☐ Defer	No ☐
35	**Have you ever** injected or been injected with illegal or non-prescription drugs including bodybuilding drugs? If yes, please provide details …… …… ……	Yes ☐ Inform TC, consider deferral for 12 months	No ☐

36	Have you given or taken money in exchange for drugs or sex within the last **three months**? If yes, please provide details …… …… ……	Yes ☐ Inform TC, consider deferral	No ☐
37	In the past **three months** have you had a tattoo (or tattoo removal), any piercing to your ears, face or body or undergone any cosmetic treatment that involved piercing the skin **in a non-licensed establishment**? If yes, please provide details …… …… ……	Yes ☐ Inform TC	No ☐
38	In the past **three months** have you undergone acupuncture in a **non-UK establishment or by an unqualified practitioner?** If yes, please provide details …… …… ……	Yes ☐ Obtain professional reg certificate if possible. Inform TC.	No ☐
39	In the past **four months** have you been detained in a prison for more than 72 continuous hours? If yes, please provide details …… …… ……	Yes ☐ Inform TC	No ☐
40	In the past **three months** have you had sex (oral, vaginal or anal) with:		
a	*an individual who is HIV positive?*	Yes ☐ Inform TC	No ☐
b	*an individual who has had hepatitis B or C or yellow jaundice?*	Yes ☐ Inform TC	No ☐
c	*an individual who has ever been given or taken money in exchange for drugs or sex?*	Yes ☐ Inform TC	No ☐
d	*an individual who has ever injected or been injected with illegal or non-prescription drugs, including bodybuilding drugs?*	Yes ☐ Inform TC	No ☐
e	*an individual with haemophilia or a related blood clotting disorder, who has received blood products/human-derived clotting factor?*	Yes ☐ Inform TC	No ☐
f	*an individual of any race who has been sexually active in parts of the world where AIDS/HIV is very common?*	Yes ☐ Inform TC	No ☐
41	Were you born, or have you ever lived, in Africa? If yes, where?……	Yes ☐ Inform TC	No ☐
42	Have you **ever** been pregnant (including miscarriages/terminations)? If yes, how many times?..... How many live births?.....	Yes ☐	No ☐
43	Is there any possibility you could be pregnant now? Date of beginning of last menstrual period……	Yes ☐	No ☐

Covid-19 screening

44	In the past 90 days, have you had a confirmed or presumed diagnosis of COVID-19? If yes, when did you recover? ……... Has a negative test been confirmed? If yes, when was this performed? ……..	Yes ☐ Yes ☐	No ☐ No ☐
45	Have you had a positive COVID-19 Antibody test? If yes, when was this performed? ……	Yes ☐	No ☐
46	Have you had to self-isolate recently due to possible symptoms yourself, due to household members with symptoms, or due to travel or contact history? If yes, please specify the dates from/to …… ……..	Yes ☐	No ☐
47	In the past 28 days have you had known contact recently with someone with a confirmed or presumed diagnosis of COVID-19? If yes, when, and what was the nature of the contact? …….. ……	Yes ☐	No ☐
48	Have you received the Pfizer or Astra Zeneca COVID-19 Vaccine? If yes, please specify date and if this was your 1st or 2nd dose …… …… If your 1st dose, please specify when your 2nd dose is due ……	Yes ☐	No ☐

49	Do you have any of the following conditions which are thought to be risk factors for severe COVID-19 disease? 1) Aged 70 or older (regardless of medical conditions), or 2) under 70 with an underlying health condition listed below: ○ chronic (long-term) respiratory diseases, such as asthma, chronic obstructive pulmonary disease (COPD), emphysema or bronchitis ○ chronic heart disease, such as heart failure ○ chronic kidney disease ○ chronic liver disease, such as hepatitis ○ chronic neurological conditions, such as Parkinson's disease, motor neurone disease, multiple sclerosis (MS), a learning disability or cerebral palsy ○ diabetes ○ problems with your spleen – for example, sickle cell disease or if you have had your spleen removed ○ a weakened immune system as the result of conditions such as HIV and AIDS, or medicines such as steroid tablets or chemotherapy ○ a body mass index (BMI) of 40 or above ○ pregnant If yes, please provide more details …….. ……..	Yes ☐	No ☐

DONOR'S STATEMENT OF UNDERSTANDING

I have had the opportunity to ask questions about the information requested on the questionnaire "Donor Health History".
I understand that the requested information is important if I am at risk for infection due to HIV, Hepatitis B or C, or any other communicable disease agents or diseases, my donated cells may transmit these diseases to the patient receiving the cells.

If at any time during the donation process I develop any of the following symptoms:
A cough, fever or difficulty breathing, I will contact my Donor Provision coordinator.

I have truthfully answered all the questions on this questionnaire.

I authorise the release of information on the questionnaire to the overseas Registry (which may be outside the European Union) and its agents and representatives and other medical facilities known as transplants centres. This release may only be in connection with the possibility of the donation of my blood stem cells to a patient. I understand that any information identifying me will remain confidential and only my unique

donor identification number will be used on any information passed to the overseas Registry. I also understand that the potential recipient of my donation may be advised of any communicable risk.

I understand that authorising this release of information is voluntary and that I can refuse to sign this document.

Donor Details	
Name	fullname
GRID	an_gridformatted
Donor ID	an_donorinternationalregistryid
Signature	

Witnessed by	
Name	
Signature	
Job Title	
Date	

If the donation date has been postponed since the original medical, please complete the following:

☐ I confirm there have been no changes to the above information provided, and I have advised the Collection Centre/AN of all health changes (if any) since my original medical

Donor name	
Signature*	
Date	

* If you're completing online and unable to insert a signature please just initial this box.

MEDICAL UPDATE FORM

Donor ID

saving the lives of people with blood cancer

DONOR INFO

Donor ID			
Date of birth		Gender	M ☐ F ☐
Title	Mr ☐ Ms ☐ Miss ☐ Mrs ☐ Dr ☐ Other (please state) ☐		
First name(s)			
Last name			
Previous name(s)			
Date of birth		Age	
Height		Weight	

NB: MINIMUM weight is 7st 12lbs (50kgs).Volunteers who are severely overweight may not be accepted as this can seriously increase risk of complications associated with the administration of general anaesthetic.

Occupation	

DATA PROTECTION STATEMENT

By being on the register you agree to receiving register related communications from us. We will only send you information on our fundraising and other ways you can support if you have told us you are happy to receive this. If you would like to hear more about our lifesaving work, including news, fundraising and other ways you can support us, let us know if you're happy for us to contact you by:

	Yes	No
Email	☐	☐
Text Message	☐	☐
Phone	☐	☐

From time to time, we will also send you information about our lifesaving work, including news, fundraising and other ways you can support us, by post. Please tick this box if you would prefer not to get post from us. ☐

Your details are safe with us. We promise to protect and respect your privacy. Please refer to our Privacy Policy for more information about how we process your data. You can update your preferences at any time by emailing donor.support@anthonynolan.org.

HOME/PERMANENT ADDRESS (if you require the blood sample kit to be sent to a different address please contact your Coordinator)

Address			
		Post code	

TELEPHONE + EMAIL

Mobile	
Home	
Work	
Email (work)	
Email (personal)	

ALTERNATIVE CONTACT DETAILS

We always need to be able to contact you in case you come up as a potential match. That's why it's so important that you keep your details up to date, and that you provide us with an additional contact (friend or relative), just in case. We will only contact them if you came up as a match, and we can't get in touch with you. We will never contact this person for marketing or fundraising, and we will never pass on any of your personal details. Please make sure this contact lives in the UK and doesn't have the same address as you. We also ask that you have, or will, let them know you've provided Anthony Nolan with their details and ensure that they are happy to be contacted if we can't get in touch with you.

Name			
Relationship to you			
Address			
		Post code	
Mobile			
Home phone			
Email (work)			
Email (personal)			

YOUR GP

Name of GP	
Name of Practice	
Address	
Post Code	
GP's telephone	
Your NHS number, if known	

DONOR CONSENT

Are you on any other register for bone marrow/blood stem cell donors?	Yes ☐ No ☐
If yes, please provide dates/details:	
I have read the 'The Little Guide to What Happens Next' booklet and I understand that to donate bone marrow/stem cells I would be required to: **1**) Undergo a medical examination in a designated specialist hospital to assess my fitness to donate. **2**) Spend two nights in a hospital and undergo a general anaesthetic for a bone marrow harvest/or receive a 4/5 day course of injections of a growth factor followed by a peripheral blood stem cell collection (PBSC). **3**) Take time away from work or my normal activities: (7 days for bone marrow/1-2 days for PBSC)	Yes ☐ No ☐
My preferred method of donation is: We strongly advise that all our Donors discuss this request and the stem cell donation procedure with friends or family. All information can be found in the booklet 'The Little Guide to What Happens Next'	Bone marrow ☐ PBSC ☐ No preference ☐
Do you have any unavailability (holidays etc.) within the next 6 months?	Yes ☐ No ☐
If yes, please provide dates/details:	

- To the best of my knowledge I am not at risk of transmitting any infectious diseases.
- I understand that I may be required to give several blood samples over a period of time for further tests and I am willing to undertake this as and when requested.
- I understand that I may be found to be compatible with any person in need of a bone marrow / blood stem cell transplant, in any part of the world. I am willing to donate to anyone for whom I am considered a suitable match
- If I am identified as a possible match but cannot be found, I agree Anthony Nolan may get my contact details from local health authorities including my GP surgery.
- I agree to the storage of frozen samples of my blood / DNA and understand that these may be used for more detailed tissue typing at a future date.

- We will never sell or pass on your personal information to third parties for their own marketing purposes. I understand that my personal data may be shared with third party organisations to facilitate my status as a potential donor on the register and only in accordance with applicable data protection and related laws and guidance (see DONOR PRIVACY below).
- I understand that I have the right to access my medical information in accordance with applicable data protection and related laws and guidance (see DONOR PRIVACY below).
- I give permission for my blood to be screened during further tests for infectious disease markers including Hepatitis B, Hepatitis C and HIV.
- I understand that I may be contacted in complete confidence by the Medical Director or Medical Officer of Anthony Nolan for any appropriate consultation and guidance during this process. This includes discussing positive* infectious disease marker test results. Should the test appear to be positive, we will email you to check when and how you would like the Medical Director or Medical Officer to contact you. The Medical Director or the Medical Officer may also contact my GP if he/she is having difficulty contacting me.

***Please note that a substantial proportion of the tests which initially appear positive are, on re-testing, not confirmed as positive.**

STATEMENT BY DONOR: PRIVACY

I have read and understood the Anthony Nolan Privacy Policy (available online at https://www.anthonynolan.org/privacy) and each of the sections above and I understand and agree to them.

I **give my consent** to the use of the following data by Anthony Nolan

- The data I have provided in this form; ☐
- Any analysis of the blood sample I donate, which I understand will be tested for markers of infection including Syphilis, HIV, Hepatitis B & C, which I specifically consent to the use of; ☐
- The results of such blood tests which I **specifically consent** to Anthony Nolan sharing with my GP; and ☐
- Any analysis of the blood cells I donate, which I understand may be stored by the Transplant Centre ☐

I understand that Anthony Nolan will use and store my personal data in accordance with the Anthony Nolan Privacy Policy and that I may withdraw my consent to the use of my personal data, at any time, in accordance with the terms of this policy.

Please sign here if you agree to the donor consent statement above:

Please sign here if you agree to the donor consent statement above:		**Date**	

PARENT/GUARDIAN

Are you under 18?	Yes ☐ No ☐	We strongly advise that all of our Donors discuss this request and the stem cell donation procedure with friends or family. All information can be found in the 'The little guide to what happens next' booklet

If you are under the age of 18 and you are found to be a match and selected for donation you would need to be accompanied by your parent or guardian (over the age of 18).

Do we have your permission to discuss this with your parent or guardian if you are chosen for donation?	Yes ☐ No ☐

Parent or Guardian full name			
Relationship to you			
Address			
		Post code	
Mobile			
Home phone			
Email			

MEDICAL UPDATE

1. Have you ever had, or do you suffer from:

a) Ankylosing Spondylitis?	Yes ☐ No ☐	m) Schizophrenia or other mental illness under psychiatric care?	Yes ☐ No ☐
b) Cancer? (excluding Basal Cell Carcinoma of the skin)	Yes☐ No ☐	n) Sickle Cell Anaemia (tick 'no' if you only have the trait or are a carrier)?	Yes ☐ No ☐

c) Crohn's Disease or Ulcerative Colitis?	Yes ☐ No ☐	o) Lupus (SLE , Systemic Lupus Erythematosus)?	Yes ☐ No ☐
d) Diabetes (insulin dependent or medication controlled)?	Yes ☐ No ☐	p) Thalassemia (tick 'no' if you only have the trait or are a carrier)?	Yes ☐ No ☐
e) Myasthenia Gravis?	Yes ☐ No ☐		
f) Pernicious Anaemia?	Yes ☐ No ☐		
g) Severe Psoriasis?	Yes ☐ No ☐	**2. Do you have a family history of blood cancer or an inherited blood disorder?**	Yes ☐ No ☐
h) Severe Eczema?	Yes ☐ No ☐	If yes, relationship to you?	
i) Rheumatoid or Psoriatic Arthritis?	Yes ☐ No ☐		
j) Reactive Arthritis (Reiter's Syndrome)	Yes ☐ No ☐	**3. Have you ever used a needle to take anything other than prescribed medication?**	Yes ☐ No ☐
k) Rheumatic Fever?	Yes ☐ No ☐		
l) Sarcoidosis?	Yes ☐ No ☐	**4. Have you ever given or taken money or drugs in exchange for sex?**	Yes ☐ No ☐

5. Have you ever had sex with:

a) An individual who may be HIV positive	Yes ☐ No ☐	d) An individual who has ever used a needle to take drugs not prescribed by a doctor	Yes ☐ No ☐
b) An individual who may have had Hepatitis B or C or Yellow Jaundice	Yes ☐ No ☐	e) An individual with haemophilia or a related blood clotting disorder, who has received blood products/human derived clotting factors	Yes ☐ No ☐
c) An individual who has been given money or drugs in exchange for sex	Yes ☐ No ☐	f) An individual who has been sexually active in parts of the world where AIDS/HIV is very common	Yes ☐ No ☐

6. Have you ever had a <u>positive test</u> result for:

a) HIV	Yes ☐ No ☐	c) Hepatitis B	Yes ☐ No ☐
b) HTLV	Yes ☐ No ☐	d) Hepatitis C	Yes ☐ No ☐

If your answer is 'yes' to any of the above please contact your Coordinator before completing this form.

7. Prep Questions:

Are you currently taking PrEP?	Yes ☐ No ☐
Have you taken PrEP in the last 3 months?	Yes ☐ No ☐
If yes to the above question, date last taken?	

If your answer is 'yes' to question 7 please contact your Coordinator before completing this form.

8. Hepatitis E Virus advice

There has been a rise in the number of people acquiring the Hepatitis E virus in the UK over the last few years. The most common way people catch this infection in the UK is through eating raw or undercooked meat (particularly pork products) and shellfish. Please can we ask you to be really careful. Most healthy people infected with hepatitis E have no symptoms, and the infection clears within a couple of months, but it can be very risky if transmitted to patients having a stem cell transplant.

Please tick the box to confirm you've read this information Yes ☐ No ☐

9. Do you, or have you ever suffered from any form of lower back injury or sciatica? (if no go to next question) Yes ☐ No ☐

Note: People with lower back problems have to be carefully screened for their own safety as bone marrow is drawn from the pelvic bone. For this reason please give us as much detailed information as possible (if you do have back problems you may be only able to donate via the PBSC method).

If yes, a) when did the problem start?		b) Was there a cause (e.g. accident, or sports injury)?	Yes ☐ No ☐
If yes, please provide details			
c) What investigations have been made, and what were the results?			

d) What diagnosis or name has the condition been given?	
e) What treatment have you received? e.g. surgery, manipulation (chiropractic care, physiotherapy, osteopathy etc.)	

f) Do you still suffer from pain and discomfort?	Yes ☐ No ☐	g) Can you lift heavy objects or participate in vigorous sports?	Yes ☐ No ☐	h) Does the problem cause any limitations to your lifestyle?	Yes ☐ No ☐

g) If yes, please describe the limitations	
h) How much time have you had off work or normal duties?	
i) Please list any medication you take for your back condition (name and dose)	
j) Has your back problem been resolved?	Yes ☐ No ☐

10. Do you drink alcohol? Yes ☐ No ☐

If yes, how many units per week? (1 unit = 1 small glass of wine/half-pint of beer)

11. Have you had any pregnancies? (If no, go to next question) Yes ☐ No ☐

If yes, please state the number, including any terminations or miscarriages

Date of last birth:		It is our standard policy not to test donors who are pregnant or who have a baby less than six months old. Please advise us if this is the case and you are, therefore, not able to provide a blood sample currently.	Yes ☐ No ☐

12. Have you ever donated blood? Yes ☐ No ☐ If yes, when did you last donate?

13. Have you ever been refused as a blood donor? Yes ☐ No ☐

If yes, please state when and why

14. Have you ever received any blood transfusions (including plasma or other blood products)? Yes ☐ No ☐

If yes, why, when (approximately what year), how many units and in which country?

15. Have you had a tattoo, body piercing or acupuncture in the last 3 months?

Tattoo	Yes ☐ No ☐	Body piercing	Yes ☐ No ☐	Acupuncture	Yes ☐ No ☐

If yes to any of the above, was it at a licensed establishment?	Yes ☐ No ☐	Please provide the date and name of the person and the establishment where this took place?	

16. Have you ever had anaemia or any blood disorder? Yes ☐ No ☐

If yes, please give details/date

17. Are you a carrier of:

Sickle cell trait	Yes ☐ No ☐	Thalassemia trait	Yes ☐ No ☐
Have you ever had malaria?	Yes ☐ No ☐	If yes, when?	

18. Have you or anyone in your family had CJD (Creutzfeld-Jakob Disease)? Yes ☐ No ☐

If yes, relationship to you?

19. Have you ever had brain surgery? Yes ☐ No ☐

If yes, please provide details

20. Have you ever had epilepsy? (If no go to next question) Yes ☐ No ☐

a) When was the last fitting episode?		b) Are you on medication for epilepsy?	Yes ☐ No ☐	If yes, please give medication name and dosage	

21. Have you ever been treated with human pituitary extracts, such as growth hormones or gonadotrophins? Yes ☐ No ☐

If yes, please give start and end dates

22. Do you have any thyroid conditions including Graves' and Hashimoto's Disease? (if no go to next question) Yes ☐ No ☐

a) If yes, have you ever received radioiodine, carbimazole or propylthiouracil?	Yes ☐ No ☐	b) What other treatment or medication have you received?	

23. Do you suffer from depression? (If no, go to next question) Yes ☐ No ☐

a) If yes, what medication, if any, have you been prescribed (name and dose)?			
b) Are you receiving any therapy or counselling for your depression?	Yes ☐ No ☐	c) Do you feel your depression is well-controlled?	Yes ☐ No ☐

24. Do you have any allergies (including any severe or life-threatening allergies such as latex and general anaesthetic)? Yes ☐ No ☐

If yes, what are the triggers?

25. Do you have Coeliac Disease? Yes ☐ No ☐

26. Do you suffer from asthma? (If no, go to next question) Yes ☐ No ☐

a) If yes, is it well-controlled?	Yes ☐ No ☐	b) Have you ever had an asthma attack requiring admission to hospital?	Yes ☐ No ☐
If yes, when were you last admitted to hospital?		c) Have you ever had an asthma attack requiring admission to a high dependency or an intensive care unit?	Yes ☐ No ☐
d) Do you use inhalers?	Yes ☐ No ☐	If yes, please give details	
e) Do you use Theophylline tablets? (e.g. Nuelin SA, Slo-Phyllin, Uniphyllin Continus)	Yes ☐ No ☐	f) Montelukast tablets?	Yes ☐ No ☐

g) Steroid tablets or injections? For example, Prednisolone	Yes ☐ No ☐	h) Any other asthma medication?	Yes ☐ No ☐
Please give details			

27. Have you ever had Tuberculosis?	Yes ☐ No ☐	If yes, when?	
28. Have you ever suffered from any other lung conditions?	Yes ☐ No ☐	If yes, please provide details	
29. Do you suffer from high blood pressure? (if no, go to next question)	Yes ☐ No ☐	a) If yes, is it being monitored by your GP?	Yes ☐ No ☐
b) Please give date and details of your last reading (please ask your GP or practice nurse)			
c) Are you on medication for high blood pressure? If yes, please give medication name and dosage	Yes ☐ No ☐		

30. Have you ever had:

a) A heart attack?	Yes ☐ No ☐	b) Chest pain?	Yes ☐ No ☐
c) Angina?	Yes ☐ No ☐	d) A heart murmur?	Yes ☐ No ☐
e) Any heart surgery (including keyhole) or any other procedure (e.g. angioplasty)?	Yes ☐ No ☐	f) Any other heart disease/condition?	Yes ☐ No ☐
If yes to any above questions; please give details or example, date of diagnosis, details of an investigations (e.g. ECG – Electrocardiograph)			

31. Have you ever had a blood clot (e.g. deep vein thrombosis or pulmonary embolus)? (If no, go to next question)			Yes ☐ No ☐
a) Has this happened on more than one occasion?	Yes ☐ No ☐	b) Where was the most recent clot (e.g. lower leg)?	
c) When did this occur?		d) Were there any factors that may have contributed to this event?	Yes ☐ No ☐
If yes, please give details			
32. Do you suffer from gout? If yes, please be aware that you will only be able to donate bone marrow, not PBSC.			Yes ☐ No ☐
33. Have you ever had ME or Post-viral Syndrome?			Yes ☐ No ☐
If yes, is it	Ongoing ☐ Resolved ☐		
34. Have you ever been bitten by an animal? (if not go to next question)			Yes ☐ No ☐
If yes, by what animal and when?			
35. Have you been diagnosed with any condition not stated in this questionnaire?			Yes ☐ No ☐
If yes, please provide details			
36. Are you taking any other medication not previously mentioned?			Yes ☐ No ☐
If yes, please provide details			

37. Have you undergone / are awaiting any surgery including dental? Yes ☐ No ☐

Please state the nature of the condition; if it is ongoing or intermittent; and any limitations it imposes on your lifestyle/activities. Additionally, please make it clear whether the condition has now cleared and if so how long it lasted.

Date of diagnosis		Details of any medications, including doses	

38. Are you currently undergoing any medical investigations or have an undiagnosed medical condition Yes ☐ No ☐

If yes, please provide details

Signature required **Date**

YOUR ETHNIC ORIGIN

POTENTIAL BLOOD STEM CELL/BONE MARROW DONOR

It's really important for us to understand your ethnic background as it helps us identify the best matches. This is a description that you think best describes your ancestors' origins and is not necessarily your nationality.

Please only tick one.

UK & Ireland (WHITE)	England ☐ Scotland ☐ Wales ☐ Northern Ireland ☐ Republic of Ireland ☐ Mixed UK & Ireland (e.g. Welsh mother and English father) ☐
European (WHITE)	Austria ☐ Belgium ☐ France ☐ Germany ☐ Netherlands ☐ Switzerland ☐ Scandinavia (e.g. Denmark, Norway, Sweden, Finland, Iceland) ☐ Italy, Portugal, Spain ☐ Turkey ☐ Greece ☐ Other Balkan States (e.g. Serbia, Bulgaria) ☐ Other Southern or Eastern descent, or a mixture of those ☐ Other Northern or Central European descent ☐
Other (WHITE)	Australia, New Zealand (Northern Europe descent) ☐ Other white (inc. Mixed White) ☐
African-Caribbean & African (BLACK)	Caribbean Islands ☐ Africa (excluding North Africa) ☐ Any other African or African-Caribbean family origins (excluding North Africa) ☐
Asia (ASIAN)	India ☐ Pakistan ☐ Bangladesh ☐ Any other South Asian family origins or combination of those above (e.g. Nepal, Bhutan) ☐ Japan, North Korea, South Korea ☐ China, Taiwan ☐ Thailand, Indonesia, Burma ☐ Malaysia, Vietnam, Philippines, Cambodia, Laos ☐ Any other East Asian family ☐ Eastern Russia, Kazakhstan, Uzbekistan, Mongolia ☐ Other Asian (inc. Mixed Asian) ☐
Other	North Africa & Middle East ☐ Jewish ☐ South America ☐ Central America, Mestizo ☐ Any other Non-European ☐
Mixed ethnicity	Mixed White & Asian ☐ Mixed Black & Asian ☐ Mixed White & Black ☐ Mixed White & Other ☐ Mixed Black & Other ☐ Mixed Asian & Other ☐ Any Other mixed origins ☐
Don't know	☐
Declined to answer	☐

Tissue Donor Number | | | | | | | | | |

ODT Donor Number | | | | | | |

Medical and Social History Questionnaire

Directions for completion

1. This form must be completed in **black or dark blue ink** by the Specialist Requestor (SR)/Specialist Nurse – Organ Donation (SNOD)/Specialist Nurse – Tissue Donation (SNTD)/Tissue Donor Co-ordinator (TDC) and signed where required.

2. The original copy should be retained by the **SR/SNOD/SNTD/TDC** for the donor file.

3. In the event of organ and tissue donation, a legible copy should be sent to the relevant **Tissue Establishment**, where required.

NOTE: The term patient is used throughout the form to refer to the potential donor.

The term relative is used throughout the form to refer to the relationship between the patient and the interviewee.

Tissue Donor Number | | | | | | | | | |

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In order to ensure the safety of organs and tissue for transplant I will need to ask you some questions about *(name of patient)* medical and lifestyle history. Some of the questions are of a sensitive and personal nature. They are similar questions to those asked when someone donates blood. I will read and discuss each question with you and ask that you answer to the best of your knowledge with either a "Yes" or "No."

PATIENT INFORMATION

Patient's Forename(s) Please Print

Patient's Surname Please Print

Donating Hospital

NHS/CHI Number

Hospital Number

Date of Birth (dd/mm/yyyy)

Cause of Death

Occupation

Country of Birth

Country of residence

INTERVIEWEE INFORMATION

Information discussed with

Name Please Print

Relationship Please Print

For patients under the age of 18 months, or those who have been breast-fed or fed breast milk by a donor in the last 12 months, the mother is required to answer these questions with regard to her own and her child's health.

For children: has your child been breast-fed in the past 12 months? N/A ☐ No ☐ Yes ☐ Unknown ☐

NOTE: for all patients under the age of 18 months and any child who has been breast-fed in the last 12 months, a blood sample for microbiological testing is required from the mother, as well as from the patient.

For ALL female patients between 12 and 55 years of age*: Is there a possibility that your relative could be pregnant? N/A ☐ No ☐ Yes ☐ Unknown ☐

*DonorPath currently displays age range 13-53 years. This does not reflect current clinical guidance of 12-55 years documented in **MPD891**

Tissue Donor Number | | | | | | | | | |

ODT Donor Number | | | | | | |

GENERAL HEALTH INFORMATION

1) Did your relative visit a general practitioner in the last two years? No ☐ Yes ☐ Unknown ☐

If YES, give details

2) Was your relative currently seeing or waiting to see a general practitioner or any other healthcare professional? No ☐ Yes ☐ Unknown ☐

If YES, give details

3) Did your relative ever take regular medication? No ☐ Yes ☐ Unknown ☐

If YES, give details of any current or previous medication including any medication for acne, prostate or psoriasis

4a) Did your relative have a history of allergies to medication, food or other substances No ☐ Yes ☐ Unknown ☐

If YES, please provide details of the substance they were allergic to and describe the reaction

4b) Did your relative have any health problems due to exposure to toxic substances such as pesticides, lead, mercury, gold, asbestos, cyanide, agent orange etc? No ☐ Yes ☐ Unknown ☐

If YES, please provide details of the toxic substance and treatment

5a) Was your relative a diabetic? No ☐ Yes ☐ Unknown ☐

If YES, were they on insulin? N/A ☐ No ☐ Yes ☐ Unknown ☐

5b) Is there a family history of diabetes? No ☐ Yes ☐ Unknown ☐

If YES, is it insulin-dependent diabetes? N/A ☐ No ☐ Yes ☐ Unknown ☐

6. Did your relative suffer from any chronic or autoimmune illness or disease of unknown cause? No ☐ Yes ☐ Unknown ☐

If YES, give details including hospital name and dates of treatment if possible

7. Did your relative ever suffer from any bone, joint, skin or heart disease? No ☐ Yes ☐ Unknown ☐

If YES, specify which and give details

Tissue Donor Number | | | | | | | | | |

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8) Did your relative ever have hepatitis, jaundice or liver disease? No ☐ Yes ☐ Unknown ☐

If YES, give dates, diagnosis, treatment and hospital /clinic name if known

9) Did your relative recently suffer from significant unplanned weight loss? No ☐ Yes ☐ Unknown ☐

If YES, give details

10) Did your relative ever undergo any investigations for cancer or were they ever diagnosed with cancer? No ☐ Yes ☐ Unknown ☐

If YES, give details including hospital name and dates of treatment, if possible

11) Did your relative have a history of eye disease, receive any medications for eye problems (e.g. eye drops), or undergo eye surgery or laser treatment? No ☐ Yes ☐ Unknown ☐

If YES, give details including hospital name and dates of treatment, if possible

12) Did your relative ever have any operations? ***If NO go to question 15*** No ☐ Yes ☐ Unknown ☐

If YES, give details including hospital name and dates of treatment, if possible

13) Did your relative ever have any surgery on the brain or spine? N/A ☐ No ☐ Yes ☐ Unknown ☐

If YES, give details including hospital name and dates of treatment if possible. **Surgery before 1993** is particularly significant

14) Did your relative ever have an organ or tissue transplant? N/A ☐ No ☐ Yes ☐ Unknown ☐

If YES, give details including hospital name and dates of treatment if known

15) Was your relative ever told not to donate blood? No ☐ Yes ☐ Unknown ☐

If YES, give details of where, when and the reason

16) Did your relative receive a transfusion of blood or blood product(s) at any time? No ☐ Yes ☐ Unknown ☐

If YES, give details including country, hospital name, dates and reason for transfusion

Tissue Donor Number | | | | | | | | | |

ODT Donor Number | | | | | | |

17) Did your relative suffer from any type of brain disease such as Parkinson or Alzheimer disease or dementia? No ☐ Yes ☐ Unknown ☐

If YES, give details including hospital name and dates of treatment if possible

18) Did your relative suffer from any one or more of the following problems: memory problems or confusion, change in personality or behaviour, or were they unsteady on their feet? ***If NO go to Question 19, if YES*** No ☐ Yes ☐ Unknown ☐

18a) When did these symptoms start?

Please give details

18b) Did they worsen noticeably over time? No ☐ Yes ☐ Unknown ☐

Please give details

18c) Was your relative able to live independently? No ☐ Yes ☐ Unknown ☐

Please give details

18d) Were you aware of a condition causing these symptoms? No ☐ Yes ☐ Unknown ☐

If YES, please specify condition

19) Did your relative have a family history of prion disease, such as CJD, or were they ever told that they were at risk of prion disease? No ☐ Yes ☐ Unknown ☐

If YES, give details

20) Did your relative ever receive human pituitary extracts, e.g. growth hormones or fertility treatment or test injections for hormone imbalance? No ☐ Yes ☐ Unknown ☐

If YES, give details including dates and hospital/clinic name if known

21) Did your relative ever have any significant infection? No ☐ Yes ☐ Unknown ☐

If YES, give details, and any treatment received and hospital/clinic name if known

Tissue Donor Number | | | | | | | | | |

ODT Donor Number | | | | | | |

RECENT HISTORY

22) Did your relative come into contact with an individual with an infectious disease within the last month? No ☐ Yes ☐ Unknown ☐

If YES, please specify details, dates, symptoms, diagnosis, and treatment

23) Did your relative have any signs of infection, e.g. colds, flu, fever, night sweats, swollen glands, diarrhoea, vomiting or skin rash within the last month? No ☐ Yes ☐ Unknown ☐

If YES, please specify dates, symptoms, diagnosis, and treatment

24) Did your relative have any immunisations within the last 2 months? No ☐ Yes ☐ Unknown ☐

If YES, give details including travel vaccinations and flu vaccination or flu nasal spray

25) Did your relative have tattooing, body piercing, botox injections, acupuncture, colonic irrigation, faecal transplantation, or any other cosmetic treatments or injuries that involve piercing the skin in the last 3 months? No ☐ Yes ☐ Unknown ☐

If YES, give details including where and when including unlicensed clinics in UK or abroad

26) In the last 12 months has your relative been bitten or scratched by any animal (strays, pets, wild, farm or ticks) or been bitten by a human. Or, has your relative ever been bitten or in close contact with bats anywhere in the world or been bitten by a mammal outside the UK? No ☐ Yes ☐ Unknown ☐

If YES, give details of incident, circumstances, animal, place, dates and treatment

Tissue Donor Number | | | | | | | | | |

ODT Donor Number | | | | | | |

TRAVEL HISTORY

27) Did your relative ever travel or live outside the UK (including business trips)? No ☐ Yes ☐ Unknown ☐

I***f NO go to question 33***

28) In the last 12 months did your relative go outside the UK (including business trips)? N/A ☐ No ☐ Yes ☐ Unknown ☐

Give details of dates and destinations visited

29) Did your relative ever have malaria or an unexplained fever which they could have picked up whilst abroad? N/A ☐ No ☐ Yes ☐ Unknown ☐

If YES, give date of fever/illness, places visited, duration and dates

30) Was your relative ever unwell whilst abroad or in the first month of their return to the UK? N/A ☐ No ☐ Yes ☐ Unknown ☐

If YES, give details

31) Did your relative ever live or travel outside the UK for a continuous period of 6 months or more? N/A ☐ No ☐ Yes ☐ Unknown ☐

If YES, give details of dates and destinations

32) Did your relative ever go to Central America, Mexico or South America for a continuous period of 1 month or more? N/A ☐ No ☐ Yes ☐ Unknown ☐

If YES, give details of dates, places (remote/rural/urban areas), nature of visit

33) Was your relative's mother born in Central America, Mexico or South America? N/A ☐ No ☐ Yes ☐ Unknown ☐

If YES, give details (including date)

Tissue Donor Number | | | | | | | | | |

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BEHAVIOURAL RISK ASSESSMENT

34) Did your relative

a) Consume alcohol? No ☐ Yes ☐ Unknown ☐

If YES, give details (including type and amount)

b) Smoke tobacco or any other substance? No ☐ Yes ☐ Unknown ☐

If YES, give details of substance, frequency, history of smoking time and time elapsed since giving up.

c) Take any recreational drugs? No ☐ Yes ☐ Unknown ☐

If YES, give details including route of administration and dates

35) Is it possible that any of the following apply to your relative?

a) Was, or may have been infected with HIV, hepatitis or HTLV? No ☐ Yes ☐ Unknown ☐

b) Within the last 12 months have they injected, or been injected, with non-prescription drugs, including performance enhancing drugs or injectable tanning agents? No ☐ Yes ☐ Unknown ☐

c) Been in prison or a juvenile detention centre for more than 3 consecutive days in the last 12 months? No ☐ Yes ☐ Unknown ☐

d) Taken medication to prevent HIV infection e.g. (PrEP Pre/Post exposure prophylaxis)? No ☐ Yes ☐ Unknown ☐

If YES to any of the above questions a-d, give details, including dates.

36) Has your relative **ever** had sex – consensual or otherwise? N/A ☐ No ☐ Yes ☐ Unknown ☐

If NO, go to question 38.

If **YES**, is it possible that your relative:

a) Was given payment for sex with money or drugs in the last 3 months? N/A ☐ No ☐ Yes ☐ Unknown ☐

b) Ever had a sexually transmitted disease? N/A ☐ No ☐ Yes ☐ Unknown ☐

c) Ever had sex with anyone who was diagnosed with a Viral Haemorrhagic Fever N/A ☐ No ☐ Yes ☐ Unknown ☐

If YES, to any of the above, give details, including dates and where appropriate hospital/clinics, treatments.

Tissue Donor Number | | | | | | | | | |

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37)	Did your relative have sex, consensual or otherwise in the last 3 months?	N/A		No		Yes		Unknown	
	If no, go to question 38. If yes, is it possible that in the last 3 months your relative had sex with								
a)	*(for male patients only)* another man?	N/A		No		Yes		Unknown	
b)	*(for female patients only)* a man who has ever had sex with another man?	N/A		No		Yes		Unknown	
c)	Anyone who is HIV or HTLV positive?	N/A		No		Yes		Unknown	
d)	Anyone who has hepatitis?	N/A		No		Yes		Unknown	
e)	Anyone who had a sexually transmitted disease?	N/A		No		Yes		Unknown	
f)	Anyone who has ever been given payment for sex with money or drugs?	N/A		No		Yes		Unknown	
g)	Anyone who in the last 12 months has injected or been injected with non-prescription drugs including performance enhancing drugs or injectable tanning agents?	N/A		No		Yes		Unknown	
h)	Anyone who could have had sex, in any part of the world, where AIDS/HIV is very common (this includes most countries in Africa)?	N/A		No		Yes		Unknown	
i)	Anyone who has developed an illness related to travel such as Zika?	N/A		No		Yes		Unknown	

If YES, give details

38)	Having answered all the previous questions, is there anyone else who you think may provide more information?	N/A		No		Yes		Unknown	

If YES, please specify

Tissue Donor Number | | | | | | | | | |

ODT Donor Number | | | | | | |

Question number	Relevant additional information. If any questions have been answered as unknown, give an explanation

Signature of healthcare professional obtaining information

Please Print Name

Designation of healthcare professional obtaining information

Date of interview | | | | | | | | |

Time of Interview | | | |

Tissue Donor Number | | | | | | | | | |

ODT Donor Number | | | | | | |

CALCULATION FOR PLASMA DILUTION:		
Record ALL fluid administered in the 48 hours prior to taking sample for microbiology screening		
Fluid given. (Please give name, not just colloid or crystalloid)	Date and time administered	Vol. in millilitres

Tissue Donor Number | | | | | | | | | |

ODT Donor Number | | | | | | |

Does a haemodilution calculation need to be carried out?	Yes		No		Reason	

A haemodilution calculation must be performed if the patient has:

1. Been transfused with blood or blood products.
2. Received infusions of synthetic colloids and/or crystalloids following blood loss*.

A - If the donor has received blood products/components, a pre-transfusion sample must be sought irrespective of volume of blood or blood product. This sample must be submitted for microbiological characterisation of the donor.

B - If haemodilution calculation is ≥50%, a pre-dilution sample must be sought.
If pre-transfusion or pre-dilution samples cannot be found, the Microbiology laboratory and all recipient centres/ tissue establishments must be informed and this documented.
* Decision on significance of blood loss should be discussed with clinical ITU team and made on a case by case basis.

CALCULATION FOR PLASMA DILUTION:

CRYSTALLOID INFUSED:

INTERVAL PRIOR TO SAMPLING	VOLUME INFUSED (ml)	% RETAINED	VOLUME RETAINED (ml)
>24 HOURS		0	None
2-24 HOURS		25	
1-2 HOURS		50	
<1 HOUR		75	
		TOTAL CRYSTALLOID RETAINED:	

BLOOD / COLLOID INFUSED:

INTERVAL PRIOR TO SAMPLING	VOLUME INFUSED (ml)	% RETAINED	VOLUME RETAINED (ml)
24-48 HOURS		100 (Blood) 50 (Colloid)	
0-24 HOURS		100	
TOTAL BLOOD / COLLOID RETAINED:			

Patient's weight: _____

% HAEMODILUTION

ESTIMATED TOTAL BLOOD VOLUME:
70ml per kilogram of body weight
50ml per kilogram of body weight in ICU

$$\frac{\text{(CRYSTALLOID RETAINED+ BLOOD/COLLOID RETAINED) X 100}}{\text{BLOOD VOLUME}}$$

ACCEPT (<49%)/REJECT (≥50%)

Signature of healthcare professional obtaining information

Please Print Name

Date of interview | | | | | | | | |

Time of Interview | | | | |