# Guidance for Gamete Donation in NHS Scotland



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#### **Purpose of this guidance:**

The donor's personal and family health histories are evaluated for risk of disease transmission that exceeds the general population risk. Every woman has a small chance of having a child with a birth defect, regardless of whether she conceives naturally or uses assisted reproductive technologies. It is not possible to completely eliminate these risks or to test for all of them before falling pregnant. However, a risk assessment is performed through extensive history taking and investigations as part of the donor qualification process. The goal of the risk assessment is to try to reduce the risk of significant medical problems in the donor's offspring. If a donor applicant is considered to have an increased risk of having offspring with significant birth defects, above the risk in the general population, he/she is not eligible to participate in the donor program unless there are exceptional circumstances.

Basic principles as defined in the current HFEA Code of Practice:

A donor must not be selected if they are known to have a particular gene, chromosome or mitochondrial abnormality that, if inherited by any child born as a result of the donation, may result in that child having or developing:

- a serious physical or mental disability
- a serious illness, or
- any other serious medical condition.

This document has been written as guidance; it is not possible for one document to cover off every possible medical condition that may be encountered or be relevant in a given potential donor - over and above there will always need to be medical judgement depending on individual cases which will need to be taken into consideration before making a final decision, and a donor's history needs to be updated as relevant at each and every donation e.g. exposure to or symptoms of infection, impact of new travel, recent vaccination, new medical intervention, recent high-risk activity etc..

#### How to use this guidance?

This guidance **must** be used in conjunction with the donor history questionnaire. Different medical conditions have been listed alphabetically in this document. This guidance relates to the history of both the potential donor and their biological family. Both the donor history and the family history need to be suitable to accept a potential gamete donor. Although a potential donor may be suitable for gamete donation vis-à-vis the risk of transmitting heritable conditions or infections, consideration should also be given to the donor's own health before accepting a potential donor, in particular (if relevant) their suitability to undergo ovarian stimulation and the procedure of egg collection.

A donor who may be considered unsuitable for altruistic non-directed donation may be considered suitable for altruistic directed donations with the appropriate consent in place and taking into account the welfare of any resulting children. A decision to go ahead in such a situation should be taken by a multidisciplinary team, in discussion with the recipient, and be clearly documented in the medical notes.

Refer to the Geographical Disease Risk Index for travel related infection risk exposure <u>https://www.transfusionguidelines.org/dsg/gdri</u> When a donor's visit has consisted <u>only</u> of an airport stopover there is no need to refer to the Geographical Disease Risk Index – an airport stopover is defined as a transit through an airport during which the traveller has not left the airport.

The recommended deferral periods quoted in this document are for donors who are also being tested for HIV, Hepatitis B and Hepatitis C using NAT testing; if testing for these infections is based only on serological testing then longer deferral periods are required; at present this would be a six month deferral.

This guidance has been based on the guidance for tissue and cell donors produced by the Joint United Kingdom Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee, and amended for gamete donors.

### **Red Flags:**

The following would identify the likelihood that a health condition may be hereditary. In such cases further information is required and an individualised decision should be made. These include:

- Multiple family members with the same or related disorders
- Earlier age of onset than typical
- Diagnosis in the less commonly affected sex
- Bilateral disease (e.g. breast cancer in both breasts)
- Conditions associated with one or more major birth defect
- Disease in the absence of risk factors or after preventative measures

Entries updated in version 09 (also highlighted in yellow in the document):

- 1. Monkeypox entry updated
- 2. Immunisation entry updated
- 3. Malaria entry updated
- HIV entry updated
- Hepatitis B entry updated
- Hepatitis C entry updated
- 7. Genital Warts entry updated
- 8. Tuberculosis entry updated

## Groups or Specific Conditions

A	Donor's history	Family history	Comments
Achondroplasia	Not suitable for gamete donation.	Refer to Designated Medical Officer – consider risk of hereditary transmission depending on which family members are affected.	About 80 percent of people with achondroplasia have average- size parents; these cases result from new mutations in the FGFR3 gene. In the remaining cases, people with achondroplasia have inherited an altered FGFR3 gene from one or two affected parents.
Acne	Suitable to donate gametes unless the donor is on teratogenic medication – refer to Medication entry for deferral periods required for different medications.	Not applicable.	
Adrenal disorder	Not suitable for gamete donation.	Suitable if no Red Flags.	
Albinism	Not suitable for gamete donation	Suitable if no Red Flags	
Alcoholism	Suitable for gamete donation if no high risk behaviour in donor.	Not applicable.	
Allergy	Suitable for gamete donation unless on teratogenic medication or has had an anaphylactic reaction.	Suitable if no Red Flags.	Consider getting genetic advice as regards the likely hereditary nature of anaphylactic allergic reactions.
Alzheimer's disease	Not suitable for gamete donation.	Suitable if no Red Flags.	
Anaemia	Assess the reason of anaemia; if the underlying cause does not exclude donation the donor can be accepted as a gamete donor e.g. investigated iron deficiency anaemia of known cause that is not a reason to exclude gamete donation.	Suitable if no Red Flags.	
Ankylosing spondylitis	Not suitable for gamete donation.	Suitable if no Red Flags.	

A	Donor's history	Family history	Comments
Anthrax	Acute infection with anthrax – refer to Infection Acute. If donor provides a history of exposure to anthrax with no evidence of infection – accept even if on prophylactic antibiotics.	Not applicable.	
Asthma	Refer to Allergy. Not suitable for gamete donation if very severe asthma.	Suitable if no Red Flags.	
Attention Deficit Hyperactivity Disorder (ADHD)	Not suitable for gamete donation	Suitable if no Red Flags.	
Autism spectrum condition	Not suitable for gamete donation	Refer to designated medical officer	
Avascular necrosis of the femoral head	Suitable for gamete donation if underlying cause does not exclude.	Suitable if no Red Flags.	

В	Donor's History	Family History	Comments
Babesiosis	Not suitable for gamete donation.	Not applicable.	
BCG vaccination	Not suitable for gamete donation if wound has not healed or less than 4/52 since inoculation.	Not applicable.	Consider possibility of exposure to TB – get expert opinion of risk of infection if vaccination post- exposure.
Bipolar disorder	Not suitable for gamete donation.	Suitable if no Red Flags.	
Bite – human/animal	<ul> <li>Not suitable for gamete donation if:</li> <li>ever bitten by a non-human primate</li> <li>other animal bite if wound is infected or not healed</li> <li>less than 24 months since bitten anywhere in the world by a bat</li> <li>less than 24 months since bitten by any mammal outside the UK</li> <li>less than 3 months since bitten by a human</li> <li>Get microbiology advice if donor has a history of being bitten by animals/insects/ticks in the last 12 months.</li> </ul>	Not applicable.	Being bitten by a non-human primate should result in permanent deferral. Risks include simian T-lymphotropic virus, Herpes B, simian foamy virus and other as yet unknown viruses. Non-human primates include chimpanzees, gorillas, orangutans, gibbons, monkeys (old and new world), tarsiers, lemurs and lorises.
Bleeding disorder	<ul> <li>Not suitable for gamete donation if has bleeding disorder.</li> <li>Not suitable for gamete donation if potential donor is: <ul> <li>a current or former sexual partner of a person treated with blood derived coagulation factor concentrates if it is less than three months from last sexual encounter with the partner who is being treated with blood derived coagulation factor concentrates or from inoculation injury.</li> </ul></li></ul>	Suitable if no Red Flags.	This assumes NAT testing in place - if not then a longer deferral period is indicated as per current guidance - at present this would be a deferral period of six months.
Blindness (Hereditary)	Not suitable for gamete donation.	Suitable if no Red Flags.	If family history of hereditary blindness consider route of inheritance.

В	Donor's History	Family History	Comments
Body Piercing	Not suitable for gamete donation if less than 3/12 since body piercing (including permanent and semi-permanent makeup, derma-rolling, ear/body piercing, tattoos (including memorial tattoos), platelet rich plasma facials, ritual self-flagellation etc).	Not applicable.	This assumes NAT testing in place - if not then a longer deferral period is indicated as per current guidance - at present this would be a deferral period of six months.
			If the piercing has been done in the UK on licensed premises then the donor can donate with no deferral period; if the piercing has been done outside the UK or in the UK but not on licensed premises then the donor must be deferred for three months.
Bowel polyp/cancer	Not suitable for gamete donation if suspicion of malignancy.	Suitable if no Red Flags.	
	Those with confirmed benign polyps only can donate.		
Breast lump	Not suitable for gamete donation if malignant breast lump or still under investigation re query breast lump.	Suitable if no Red Flags.	
	Those with confirmed benign breast lumps only are suitable for donation.		
Brucellosis	Not suitable for gamete donation.	Not applicable.	

С	Donor's History	Family History	Comments
Cancer	Not suitable for gamete donation if the donor has a history of cancer or clonal haematological condition or has a high risk of cancer due to family history or following genetic tests.	Suitable if no Red Flags.	
Cardiomyopathy	<ul> <li>Not suitable for gamete donation if:</li> <li>not recovered from infective cardiomyopathy</li> <li>if cardiomyopathy secondary to an infiltrative process e.g. amyloidosis/sarcoidosis</li> <li>hereditary cardiomyopathy.</li> </ul>	Suitable if no Red Flags.	
Cataract	Not suitable for gamete donation. If cataract secondary to trauma donor may be suitable to donate.	Suitable if no Red Flags.	
Central Nervous System Disease	<ul> <li>Not suitable for gamete donation if donor has: <ul> <li>dementia</li> <li>history of CNS disease of unknown or suspected infective origin (e.g. MS, optic neuritis, clinically isolated syndrome, transverse myelitis, CJD)</li> <li>neurodegenerative conditions of unknown aetiology (e.g. Parkinson's disease).</li> </ul> </li> <li>Individuals who have had Bell's palsy more than four weeks previously and have discontinued any treatment for the condition for at least seven days, even if they have residual paralysis may be accepted</li> <li>If the cause of the disease is not established, refer to a designated medical officer.</li> </ul>	Suitable if no Red Flags.	
Chagas disease	Refer to Trypanosomiasis.	Refer to Trypanosomiasis.	

C	Donor's History	Family History	Comments
Chlamydia	<ul> <li>Suitable for gamete donation:</li> <li>if there is no active infection</li> <li>&gt;12 months from last infection and negative test now</li> <li>not engaged in high risk behaviour.</li> </ul>	Not applicable.	
Chondromalacia	Suitable for gamete donation if underlying cause is not a reason for deferral.	Suitable if no Red Flags.	
CIN (Cervical intraepithelial neoplasia)	Not suitable for egg donation if undergoing investigations; if fully treated and discharged from follow up accept.	Suitable if no Red Flags.	
Cirrhosis	Not suitable for gamete donation.	Suitable if no Red Flags.	
Cleft lip	Not suitable for gamete donation if personal history of cleft lip and/or cleft palate.	Suitable if no Red Flags.	

С	Donor's History	Family History	Comments
Clubfoot	Suitable for gamete donation if not associated with other anomalies	Suitable if no Red Flags.	Clubfoot is one of the most common congenital birth defects, with an estimated birth prevalence of 1 per 1000 live births. In 20% of cases, clubfoot is associated with distal arthrogryposis, congenital myotonic dystrophy, myelomeningocele, amniotic band sequence, or other genetic syndromes such as trisomy 18 or chromosome 22q11 deletion syndrome, while in the remaining cases the deformity is isolated and the exact aetiology is unknown.
Coeliac disease	Not suitable for gamete donation if confirmed diagnosis or still under investigation.	Suitable if no Red Flags.	If there is a first degree relative with the condition there will be a 1 in 10 chance of developing Coeliac disease in their life time or of developing other autoimmune conditions.

С	Donor's History	Family History	Comments
Colitis	<ul> <li>Not suitable for gamete donation if:</li> <li>on any medication that excludes donation</li> <li>less than 2/52 since full recovery from an episode of infective colitis</li> <li>confirmed inflammatory bowel disease.</li> </ul>	Suitable if no Red Flags.	
Colostomy/ileostomy	Not suitable for gamete donation. If the reason for the colostomy is not itself a reason to exclude and the stoma is healthy accept for sperm donation only.	Suitable if no Red Flags.	
Colour blindness	Not suitable for gamete donation.	Suitable if no Red Flags.	
Complementary Therapy	Not suitable for gamete donation if the condition for which treatment was given is not acceptable. Not suitable for gamete donation if the therapies involved penetration by needles or other invasive procedures and treatment was completed less than three months prior to potential donation. If only oral or topical complementary medicines have been used donor can be accepted if the reason for which treatment was given is acceptable and the treatment is not teratogenic. If the invasive treatment was performed within the NHS or on commercial premises in the UK donor can be accepted. If the invasive treatment was performed within unlicensed, non-commercial premises in the UK or for any treatment performed outside the UK, donor can be accepted if more than three months have passed as long as NAT testing is being carried out.	Not applicable.	This assumes NAT testing in place - if not then a longer deferral period is indicated as per current guidance - at present this would be a deferral period of six months.
Congenital hip dislocation	Not suitable for gamete donation	Suitable if no Red Flags.	

с	Donor's History	Family History	Comments
Congo Fever	Not suitable for gamete donation – if less than 12/12 since recovery or from return to the UK if occurred abroad.	Not applicable.	
Contraceptive implant/injection/pill	Suitable to donate gametes. Although appropriate time interval has to be given between discontinuing contraception and gamete donation based on the type of contraception used.	Not applicable.	
Corneal transplant	Not suitable for gamete donation.	Not applicable.	
Coronary thrombosis	Not suitable for gamete donation.	Suitable if no Red Flags.	

С	Donor's History	Family History	Comments
Coronavirus Infection	<ul> <li>The most common symptoms of COVID-19 infection are: <ul> <li>Recent onset of a new, continuous cough</li> <li>High temperature</li> <li>Loss of, or a change in, normal sense of taste or smell</li> </ul> </li> <li>Please check most recently updated information re COVID-19 symptoms as they have changed over time. <ul> <li>Donor with confirmed symptomatic Coronavirus infection – must not donate if less than 28 days since resolution of symptoms; if more than 28 days have passed since resolution of symptoms; if more than 28 days have passed since resolution of symptoms and the donor remains well, accept.</li> <li>Donor with confirmed asymptomatic Coronavirus infection – must not donate if less than 28 days since confirmation of infection by positive results in a diagnostic test; if more than 28 days have passed since confirmation of infection and donor remains well and asymptomatic accept.</li> <li>Donor with suspected Coronavirus infection – must not donate if less than 28 days since resolution of symptoms; if more than 28 days have passed since resolution of symptoms and donor remains well, accept; or if more than 14 days have passed since resolution of symptoms and donor has been tested and advised they do not have coronavirus infection and the donor remains well, accept.</li> <li>Donor has had contact with a confirmed or suspected case of Coronavirus infection – must not donate if less than 10 days from the first day of isolation; if more than 10 days since the first day of isolation and the donor remained well with no symptoms of Coronavirus infection, accept.</li> </ul> </li> <li>Donor requiring isolation or quarantine after travel – must not donate during the period of isolation or quarantine as per current UK Government guidelines. See: https://www.gov.uk/guidance/travel-advice-novel-coronavirus for up to date information. This applies to asymptoms to tests positive, see guidance above. Some donors may be exempt from self-isolation due to the jobs they do – these donors should not donate until the p</li></ul>	Not applicable although consider potential exposure if donor is a close contact.	<ul> <li>Includes:</li> <li>SARS (Severe Acute Respiratory Syndrome)</li> <li>MERS (Middle Eastern Respiratory Syndrome)</li> <li>COVID-19 (infection by SARS-CoV-2)</li> <li>Confirmed infection: where the donor has been tested and found positive for the infection</li> <li>Suspected infection: Symptoms compatible with UK GOV definition who has not been tested or is awaiting test results.</li> </ul>

С	Donor's History	Family History	Comments
Coronavirus Vaccination	If a potential donor has been vaccinated through the UK vaccination program: must not donate (for sperm donors) or start stimulation (for egg donors) if less than seven days after the most recent vaccination was given; if donor felt unwell after vaccination, must not donate for 7 days after resolution of symptoms.	Not applicable.	
	<b>Recipients of any other COVID-19 vaccine outside the UK vaccination program,</b> including participants in clinical trials or donor vaccinated outside the UK: refer to a designated medical officer for individual risk assessment.		
	<b>Additional Information:</b> All COVID-19 vaccines currently licensed in the UK are considered non-live; however as the effects of these newly developed vaccines on donor health and donation safety are not fully established yet, as a precautionary principle a 7 day deferral from the date of vaccination, or 7 days from resolution of symptoms if donor develops symptoms post-vaccination, is recommended.		
	If a donor is vaccinated as part of a clinical trial or outside the UK, the type of vaccine used should be established to determine the appropriate deferral period – <u>if the vaccine uses an attenuated virus (e.g. virus vector-based other than non-replicating; or live-attenuated virus vaccines) then the donor will require a four week deferral.</u> In situations where information about the vaccine type is missing or the vaccination is experimental, a four week deferral period should be applied.		
	At the present time there is no evidence of the potential reproductive toxicology of any of the COVID-19 vaccines (including the vaccines available in the UK) – as such potential recipients should be made aware of this lack of medical knowledge.		
Crohn's disease	See colitis.	See colitis.	

D	Donor's History	Family history	Comments
Deafness	Not suitable for gamete donation if there is a hereditary cause of deafness; accept as donor if deafness is traumatic in origin.	Suitable if no Red Flags.	
Dementia	Not suitable for gamete donation.	Suitable if no Red Flags.	
Diabetes insipidus	Suitable for gamete donation only if the underlying cause does not exclude donation.	Suitable if no Red Flags.	
Diabetes mellitus	Not suitable for gamete donation.	Suitable if no Red Flags.	
Diarrhoea	Not suitable for gamete donation if chronic or associated with active inflammatory bowel disease or less than 2/52 since full recovery.	Suitable if no Red Flags.	
Disease of Unknown Aetiology	Not suitable for gamete donation.	Suitable if no Red Flags.	
Diverticulosis	Suitable to donate gametes unless underlying disease excludes.	Suitable if no Red Flags.	Age related; lifestyle acquired condition.
Drug abuse	Not suitable for gamete donation if has injected or been injected with non- prescription drugs in the past 12 months. Donor can be accepted if has not injected or been injected with non- prescription drugs (other than drugs of addiction) such as bodybuilding drugs or injectable tanning agents within the past three months. Donor can be accepted if has not injected or been injected with drugs of	Not applicable.	This assumes NAT testing in place - if not then a longer deferral period is indicated as per current guidance - at present this would be a deferral period of six months. Consideration needs to be given
	addiction within the last 12 months. Previous use of non-parenteral drugs does not necessarily require exclusion. Discuss with designated medical officer.		to the implications of the high risk behaviour.
DVT (Deep Vein Thrombosis)	Suitable for sperm donation – if the underlying cause does not exclude. Not suitable for egg donation	Suitable if no Red Flags.	
Dwarfism	Not suitable for gamete donation.	Suitable if no Red Flags.	

D	Donor's History	Family history	Comments
Dysplasia of the hip	Suitable to donate gametes if due to trauma; if congenital/hereditary cause defer.		12% risk of child being affected; hip dysplasia is 12 times more likely when there is a family history.

E	Donor's history	Family history	Comments
Ebola	Please refer to Viral Haemorrhagic Fever.	Please refer to Viral Haemorrhagic Fever.	
Eczema	<ul> <li>Not suitable for gamete donation if:</li> <li>on teratogenic medication</li> <li>underlying condition prevents being a donor</li> <li>very severe eczema that is affecting quality of life</li> </ul>	Suitable if no Red Flags.	
Endocarditis	Not suitable for gamete donation during active infection – accept if more than two weeks since confirmed full resolution unless there is underlying Congenital Heart Disease.	Suitable if no Red Flags.	
Ehlers-Danlos Syndrome	Not suitable for gamete donation.	Suitable if no Red Flags.	
Electrolysis	Suitable for gamete donation.	Not applicable.	
Emphysema	Not suitable for gamete donation.	Suitable if no Red Flags.	
Endometriosis	Suitable for egg donation.	Not applicable.	
Epilepsy	<ul> <li>Not suitable for gamete donation if:</li> <li>of recent onset and not fully investigated or secondary to malignancy or degenerative neurological disease</li> <li>on teratogenic treatment.</li> </ul>	Suitable if no Red Flags.	Consider the possibility of hereditary element of the epilepsy.
Eye disease	Not suitable for gamete donation if active ocular inflammation, history of malignancy, transplanted ocular tissue – if being treated with eye drops determine what the condition is and discuss with designated medical officer.	Suitable if no Red Flags.	

F	Donor's history	Family history	Comments
Factor V Leiden	Not suitable for gamete donation.	Suitable if no Red Flags.	Autosomal dominant and recessive inheritance patterns.
Fibroid uterus	Suitable for gamete donation if transvaginal egg collection is feasible.	Not applicable.	
Fibromyalgia	Suitable to donate gametes.	Suitable if no Red Flags.	
Filariasis	Not suitable for gamete donation.	Not applicable.	

G	Donor's history	Family history	Comments
G6PD deficiency	Not suitable for gamete donation.	Suitable if no Red Flags.	
Gall bladder disease	Suitable to donate gametes if has recovered or has asymptomatic gallstones that are not due to a hereditary condition and gall bladder disease not due to malignancy.	Not applicable.	
Gall stones	Suitable for gamete donation unless hereditary cause for gallstones.	Suitable if no Red Flags.	
	If recent acute cholecystitis episode refer to Infection Acute.		
Gaucher's disease	Not suitable for gamete donation.	Refer to Designated Medical Officer – consider risk of hereditary transmission depending on which family members are affected.	
Genetic condition	Not suitable for gamete donation is donor has a genetic condition that leads to a significant medical condition.	Suitable if no Red Flags.	Consider potential of donor carrying relevant genetic abnormality present in family.
Genital warts	Not suitable for gamete donation if there is evidence of high-risk behaviour and/or evidence of current infection.	Not applicable.	
Giardiasis	Suitable to donate unless active infection – refer to Infection Acute.	Not applicable.	
Gilbert's syndrome	Suitable to donate.	Not applicable.	Autosomal dominant or recessive inheritance; no clinical impact.
Glaucoma	Not suitable for gamete donation.	Suitable if no Red Flags.	
Gonorrhoea	Not suitable for gamete donation if less than 12 months since successfully completing treatment, as confirmed by repeat testing.	Consider risks if sexual contact.	

G	Donor's history	Family history	Comments
Gout	Not suitable for gamete donation.	Suitable if no Red Flags.	Gout runs in Families. One in five people with gout have a close family member with gout.
Granuloma inguinale	Not suitable for gamete donation.	Not applicable.	
Guillain-Barré syndrome	<ul> <li>Not suitable for gamete donation:</li> <li>if less than 24/12 from resolution</li> <li>if there has been any recurrence of symptoms</li> <li>if the doctor who managed the donor cannot confirm a typical monophasic GBS that recovered completely within 12 months</li> </ul>	Not applicable.	

н	Donor's history	Family history	Comments
Haematological disease	Not suitable for gamete donation if malignant or clonal disorder such as polycythemia vera or essential thrombocythemia. If polycythaemia or thrombocytosis are secondary to a non- malignant/clonal condition discuss with designated medical officer.	Suitable if no Red Flags.	
Haematuria	Not suitable for gamete donation if due to malignancy. If due to infection – follow acute infection guidance.	Not applicable.	
Haemochromatosis	Not suitable for gamete donation.	Suitable if no Red Flags.	
Haemoglobin disorders	Not suitable for gamete donation if has sickle cell or thalassaemia syndrome. Donors with traits for abnormal haemoglobin can be accepted; this information must be documented to ensure the future recipient/partner of recipient (as appropriate) is confirmed as not having a haemoglobin trait condition.	Suitable if no Red Flags.	
Haemolytic anaemia	Not suitable for gamete donation.	Suitable if no Red Flags.	
Haemophilia	Not suitable for gamete donation.	Not suitable for gamete donation.	
Haemorrhoids	Suitable to donate gametes provided underlying condition does not exclude donation.	Suitable if no Red Flags.	
Headache	Not suitable for gamete donation if regular headaches and not investigated yet.	Not applicable.	

н	Donor's history	Family history	Comments
Hepatitis A	<ul> <li>Donor with hepatitis A infection is not suitable for gamete donation if less than 6/12 from recovery; if fully recovered and documented HAV RNA negative and anti-HAV IgG positive after recovery can be accepted for gamete donation.</li> <li>Current/former sexual partner of Hepatitis A infected individual – Not suitable for gamete donation if less than 6/12 from recovery of current sexual partner or from last sexual contact if a former sexual partner.</li> <li>Sharing a home with a Hepatitis A affected individual – Not suitable for gamete donation if less than 6/12 from recovery of the last affected person in the house or from the last contact if no longer sharing. If shown to be immune accept.</li> <li>Hepatitis A immunisation:</li> <li>Not suitable for gamete donation if known recent exposure to Hepatitis A and less than 6 months have passed since vaccination or intramuscular immunoglobulin was given.</li> <li>If no known exposure – accept.</li> </ul>	Not applicable although consider potential exposure if donor is a close contact.	Hep A may be transmitted through sexual activity. Household contacts can easily become infected through the faeco-oral route.

н	Donor's history	Family history	Comments	
Hepatitis B infected individual	Current infection – Not suitable for gamete donation. Previous (recovered) hepatitis B infection – must not donate if less than 12 months since diagnosis; if more than 12 months since diagnosis of HBV infection and they have successfully cleared the infection accept – discuss with designated medical officer for interpretation of test results and consider the HFEA Code of Practice.	Not applicable although consider potential exposure if donor is a close <mark>or sexual</mark> contact.	potential exposure if donor is a	Sensitive assays for HBsAg may be positive following recent immunisation hence the requirement for a seven day deferral.
	<ul> <li>Current or former sexual partner of infected individual:</li> <li>must not donate if less than three months from last sexual contact; if more than three months since last sexual contact accept;</li> <li>if less than three months since last sexual contact and the donor is shown to be</li> </ul>		This assumes NAT testing in place - if not then a longer deferral period is indicated as per current guidance - at present this would be a deferral period of six months.	
	naturally immune accept. Current or former sexual partner of person who had recovered from hepatitis B infection at the time of last sexual contact:			
	<ul> <li>must not donate if less than three months from last sexual contact with a partner who has been diagnosed with HBV infection less than 12 months ago;</li> <li>if more than three months since last sexual contact regardless of when the partner was diagnosed with the HBV infection, accept; or if partner was diagnosed with HBV infection more than 12 months ago and has cleared the infection at the time of last sexual contact, accept.</li> </ul>			
	Sharing home with someone with hepatitis B infection – must not donate if less than three months since sharing ceased; if less than three months since sharing a home ceased and the donor is shown to be naturally immune, accept;			
	Hepatitis B immunisation: If immunised following known exposure - must not donate; if more than three months from immunisation accept.			
	If immunised with no known exposure - must not donate if less than seven days after the last immunisation was given; if more than seven days after the last immunisation was given accept.			

н	Donor's history	Family history	Comments
Hepatitis C	Not suitable for gamete donation. Current sexual partner of infected individual – Not suitable for donation. Former sexual partner of infected individual - only accept if BBV screen including NAT testing is negative and more than 3/12 since last sexual contact. Sharing home with someone with hepatitis C – can be accepted as donor.	Not applicable although consider potential exposure if donor is a sexual contact.	Hepatitis C is neither contagious nor spread by the faeco-oral route. It is usually only spread through a direct blood to blood route. For these reasons household contacts do not need to be deferred. This assumes NAT testing in place - if not then a longer deferral period is indicated as per current guidance - at present this would be a deferral period of six months.
Hepatitis E	Not suitable for gamete donation during acute infection. Accept if more than six months from recovery. If less than six months from recovery and HEV RNA negative and anti- HEV IgG positive accept.	Not applicable, although consider potential exposure if donor is a close contact.	
Hepatitis of Unknown Origin	Not suitable for gamete donation if <24 months from recovery. If more than 12 months but less than 24 months from recovery, obtain history and blood samples and refer to a designated medical officer: if negative for all markers of hepatitis B, including NAT, accept; if anti-HB core is positive and HBsAg is negative, HBV DNA is negative and anti- HBs has been documented at more than 100iu/l at some time accept. If more than 24 months from recovery accept. Sexual partners of affected individuals: Not suitable for gamete donation if <12 months from recovery of sexual partner. Person sharing home with affected individual: Not suitable for gamete donation if less than 12 months from recovery of the last affected person in the home.	Suitable if no Red Flags.	This assumes NAT testing in place - if not then a longer deferral period is indicated as per current guidance - at present this would be a deferral period of six months.

н	Donor's history	Family history	Comments
Hereditary elliptocytosis	Not suitable for gamete donation.	Suitable if no Red Flags.	
Hereditary spherocytosis	Not suitable for gamete donation.	Suitable if no Red Flags.	
Herpes - Genital	Not suitable for gamete donation if fresh lesions; can be accepted if lesions are completely healed provided there is no history of other STDs or evidence of high risk behaviour.	Not applicable.	
Herpes - Oral	Not suitable for gamete donation if fresh lesions – accept if lesions are healing and no evidence of high risk behaviour.	Not applicable.	
High risk activity	<ul> <li>Not suitable for gamete donation if:</li> <li>Has injected or been injected with drugs of addiction in the last 12 months</li> <li>Has injected or been injected with non-prescription drugs such as bodybuilding drugs or injectable tanning agents in the last three months</li> <li>Has received any payment for sex such as with money or drugs in the last three months</li> <li>A man has had sex with another man in the last three months (unless a repeat sample, including NAT testing, will be tested at least three months later)</li> <li>A woman has had sex (oral or anal) with a man who has had sex with another man even if they used a condom or other protective (unless a repeat sample, including NAT testing, will be tested at least three months later)</li> <li>Potential donor has had sex within the last three months with a partner who: <ul> <li>a. is or may be HIV or HTLV positive</li> <li>b. is or may be HBV or HCV positive</li> <li>c. has received any payment such as with money or drugs for sex</li> <li>d. has injected or been injected with non-prescription drugs</li> <li>e. has or may have been sexually active in parts of the world where HIV/AIDS is very common – this includes most countries in Africa.</li> </ul> </li> </ul>	Not applicable.	This assumes NAT testing in place - if not then a longer deferral period is indicated as per current guidance - at present this would be a deferral period of six months.

н	Donor's history	Family history	Comments
HIV	Not suitable for gamete donation. Current sexual partners of confirmed case: Not suitable for gamete donation. Former sexual partner of confirmed case: Not suitable for gamete donation if less than three months from last sexual contact. Sharing home with an infected person: Suitable for gamete donation if fulfil other criteria.	Not applicable although consider potential exposure if donor is a sexual contact.	This assumes NAT testing in place - if not a longer deferral period would be required as per current guidance - at present this is a six month deferral.

н	Donor's history	Family history	Comments
HIV prophylaxis	Not suitable for gamete donation if donor has taken Pre-Exposure Prophylaxis (PrEP) or Post-Exposure Prophylaxis (PEP) in the previous three months. Also assess potential donor using PrEP or PEP for donation safety risks relating to sexual activity or other high risk activity. Donor can be accepted if it is more than three months since the use of PrEP or PEP and there are no other donation safety risks.	Not applicable; although consider risk of sexual transmission if family member taking PrEP/PEP is sexual partner of potential donor.	The use of Pre-Exposure Prophylaxis (PrEP), e.g. Truvada®, to prevent HIV is increasing. Patients taking PrEP are unlikely to be eligible to donate due to donation safety guidelines. However, PrEP is also available via private prescription and/or online pharmacies and may be used by individuals who would not otherwise be deferred.
			Use of PrEP may interfere with testing for HIV by delaying seroconversion or by giving unclear results in a positive donor. For this reason, it is important that donors who have taken PrEP in the previous three months are not accepted to donate, even if they do not have another donation safety risk.
			Post-Exposure Prophylaxis (PEP) has a similar mechanism of action to PrEP and may also interfere with testing results. In the UK PEP is prescribed to people who have been exposed to someone who may have HIV. This includes through sexual activity or exposure through a needle stick injury. Donors who have received PEP will usually be ineligible to donate for the same reason they were given PEP. If the underlying reason for taking PrEP or PEP warrants a longer deferral period, this should be applied.

н	Donor's history	Family history	Comments
Homosexual/bisexual	Suitable to donate eggs. For sperm donors: suitable to donate sperm but quarantine donation for three months if doing NAT testing and repeat testing after three months; or quarantine for six months if doing only serology testing and repeat testing after six months.	Not applicable.	
Hormone treatment	Not suitable for gamete donation if has ever received human pituitary derived hormones such as growth hormones or human gondaotrophins. If treated exclusively with recombinant-derived hormones accept. In the UK recombinant growth hormone has been used since 1985. If treated with gonadotrophins that were exclusively non-pituitary derived, accept.	Not applicable.	
HRT	Not suitable for gamete donation.	Not applicable.	
HTLV	Not suitable for gamete donation. Current and former sexual partner of confirmed case: must not donate if less than 3 months from last sexual contact. Person currently or formerly sharing a home with an affected individual: accept.	Not applicable.	Consider NAT testing if a validated assay for HTLV becomes available. HTLV is neither contagious nor spread by the faeco-oral route. It is usually only spread through a direct blood to blood or sexual route. For these reasons household contacts do not need to be deferred.
Huntington's disease	Not suitable for gamete donation.	Suitable if no Red Flags.	If there is a family history of Huntington's disease consider the possibility of asymptomatic carriage of the relevant gene at the time of donation.
Hydatid disease	Not suitable for gamete donation if history of hydatid disease.	Not applicable.	
Hydrocephalus	Not suitable for gamete donation.	Suitable if no Red Flags.	

н	Donor's history	Family history	Comments
Hypercholesterolemia (Familial)	Not suitable for gamete donation.	Suitable if no Red Flags.	
Hypertension	Suitable to donate gametes provided underlying condition does not exclude donation and not needing regular medication.	Suitable if no Red Flags.	
Hypnotics	Not suitable for gamete donation while under the influence of hypnotics.	Not applicable.	
Hypospadias	Not suitable for gamete donation due to potential hereditary nature of condition and particularly if associated with undescended testis.	Suitable if no Red Flags.	

1	Donor's history	Family history	Comments
Immunisation	Live vaccine – Not suitable for gamete donation if less than 8/52 from administration; if more than 4/52 from administration of a live vaccine other than smallpox and the inoculation site has healed accept; smallpox vaccine requires an 8/52 deferral.	Not applicable.	Refer to Coronavirus Vaccination and/or Mpox entry(ies) if potential donor has been vaccinated with either of these vaccines.
	Non-live vaccine: Suitable to donate gametes and embryos except for hepatitis B within 7/7 of administration.		Please refer to the following link
	If immunisation was administered post potential exposure to infection consider the risk of infection transmission – discuss with designated		for guidance on type of immunization:
	medical officer.		<u>Appendix 3 - Table of</u> Immunisations (transfusionguidelines.org)
Immunoglobulin therapy or Immunosuppression	Not suitable for gamete donation if immunosuppressed or recovered immunodeficiency. Suitable to donate if single dose of prophylactic Ig or anti-D was the only treatment given, or if treated with intravenous immunoglobulins after 1 <sup>st</sup> January 1999 and the underlying condition is not a contraindication.	Not applicable.	Since 1999, intravenous immunoglobulins prepared from UK donors have no longer been used, as a risk reduction measure for vCJD transmission.
Infection (Acute)	Not suitable for gamete donation if less than 2/52 from recovery from a systemic infection. If the donor has cold sores, URTI such as colds and sore throats but not influenza accept if recovering.	Not applicable although consider potential donor exposure if close contact.	
Infection (Chronic)	Not suitable for gamete donation if presence of chronic infection; if the only infection is a localised superficial non-systemic fungal infection (e.g. athlete's foot or toe nail fungal infection) accept; otherwise if more than seven days from completing systemic antifungal therapy - discuss with designated medical officer.	Not applicable.	Obtain microbiology advice for any infections that are unusual or may be difficult to eradicate such as typhoid or paratyphoid.
Inflammatory bowel disease	Not suitable for gamete donation if confirmed diagnosis.	Suitable if no Red Flags.	
Inoculation injury	Not suitable for gamete donation if the injury was with material containing abnormal prions or otherwise it is less than 3 months since the date of the inoculation injury or contamination of mucosa or non-intact skin with blood or body fluids.	Not applicable.	This assumes NAT testing in place - if not then a longer deferral period is indicated as per current

I	Donor's history	Family history	Comments
			guidance - at present this would be a deferral period of six months.
Irritable bowel syndrome	Suitable to donate gametes.	Suitable if no Red Flags.	IBS is a common disorder that has been shown to aggregate in families, to affect multiple generations, but not in a manner consistent with a major Mendelian effect. Relatives of an individual with IBS are two to three times as likely to have IBS, with both genders being affected. The estimated genetic liability ranges between 1–20%, with heritability estimates ranging between 0–57%.
ITP (Immune Thrombocytopenia)	Not suitable for gamete donation if symptomatic, chronic or less than five years from recovery. Suitable for gamete donation outwith above.	Suitable if no Red Flags.	Autoimmune disorder. Consider possibility of transfusion

J	Donor's history	Family history	Comments
Jaundice	<ul> <li>Not suitable for gamete donation if jaundiced or history of jaundice;</li> <li>if the cause of the jaundice was viral, refer to the specific viral entries;</li> <li>if the cause of the jaundice was not known treat as hepatitis of unknown origin;</li> <li>if fully recovered from a non-viral cause that is not hereditary accept;</li> <li>if due to Gilbert's syndrome accept.</li> </ul>	Suitable if no Red Flags; consider potential donor exposure if close contact and infectious cause.	

к	Donor's history	Family history	Comments
Kidney disease	Depends on individual disease – discuss with designated medical officer.	Suitable if no Red Flags.	
Klinefelter's syndrome	Not suitable for gamete donation.	Not applicable.	

L	Donor's history	Family history	Comments
Leishmaniasis	Not suitable for gamete donation.	Not applicable.	
Leukaemia	Not suitable for gamete donation.	Suitable if no Red Flags.	
Lung cancer	Not suitable for gamete donation.	Suitable if no Red Flags.	
Lupus	See SLE	See SLE	
Lymphogranuloma venereum	Not suitable for gamete donation.	Not applicable.	

м	Donor's history	Family history	Comments
Malaria	Must not donate if (assuming no malaria testing; see below for discretionary* release based on additional testing): • donor has ever had malaria • donor had an undiagnosed fever (that could have been malaria) while abroad or within four months of leaving a malaria endemic area • donor has lived in any malarial endemic area for a combined period of six months or more at any time of life (whether a permanent resident or travelling through a malarial area for a combined period of at least six months). • less than 12 months since last leaving a malaria endemic area. Please refer to Geographical Disease Risk Index: https://www.transfusionguidelines.org/dsg/gdri *Discretionary release: Donors who have had malaria diagnosed in the past may be suitable to donate if it is more than four months since both antimalarial therapy was completed and symptoms caused by malaria have resolved – such donors must be tested for both malaria antibody and PCR – expert opinion will be required to interpret the results; if the donor with a history of malaria has revisited a malaria endemic area and at least four months have passed since their most recent visit to a malarial area and a validated test for malaria antibody and PCR is negative, accept. Donors who have ever flad an undiagnosed fever that could have been malaria while in a malaria area or within four months of leaving a malaria endemic area, or from the date of recover from symptoms (undiagnosed fever) that may have been caused by malaria, whichever is later, and a validated test for malaria antibody is negative, accept. If malaria antibodies are positive NAT testing and expert opinion is required. Donors who have ever lived in a malaria endemic area for six months or more (whether a permanent resident or traveling through a malarial area for a combined period of at least six months); if at least four months have passed since the date of the last potential exposure to malaria antibody test needs to be checked at every donation for donors who had prev	Not icable.	Where testing is required the results of malaria antibodies and NAT tests must be reviewed as a part of donor medical clearance to determine the suitability of donation for clinical use; expert input from relevant microbiology colleagues will be required. If the exposure, or, for donors with a history of malaria where treatment was completed and symptoms have resolved, was more than four months prior to donation and malaria antibodies are negative, NAT is not required. However, if malaria antibodies are positive and NAT is negative, in these donors, expert opinion is required to determine whether the donation can be safely released or not. If the donor is NAT positive the donation must not be released. If exposure to malaria is in the previous 4 months then the donor needs to be deferred to allow testing for malaria to be done at least 4 months post the most recent potential exposure to malaria in the first 4 months post potential exposure may lead to false negative results.

м	Donor's history	Family history	Comments
Malignant	Not suitable to donate.	Suitable if no Red Flags.	
Mantoux test	Must not donate unless test is negative and no further investigations are planned.	Not applicable, although consider potential exposure if donor is a close contact.	
Marfan's syndrome	Not suitable for gamete donation.	Refer to Designated Medical Officer – consider risk of hereditary transmission depending on which family members are affected.	Autosomal dominant.
Medication	<ul> <li>Not suitable to donate if:</li> <li>ever taken Etretinate (Tigason)</li> <li>36/12 since Acitretin (Neotigason)</li> <li>4/52 since Isotretinoin (Roaccutane) or Alitretinoin (Toctino)</li> <li>donor has needed treatment to suppress an autoimmune condition in the last 12/12</li> <li>less than 6/12 since treatment with Dutasteride (Avodart);</li> <li>less than 4/52 since treatment with Finasteride (Proscar)</li> <li>vitamin treatment- Vitamin A defer; Vitamin C or E accept.</li> <li>steroid therapy – must not donate if taking/has taken oral or parenteral steroids within the last 7/7 or if regularly taking steroid treatment (except inhalers) or the donor has needed treatment to suppress an autoimmune condition in the last 12/12; if occasional use of creams over small areas of skin for minor skin complaints accept.</li> <li>refer to HIV prophylaxis entry</li> <li>has been on methotrexate within the last 6 months</li> <li>any other teratogenic medication obtain specific advice</li> </ul>	Not applicable.	
Melanoma	Not suitable for gamete donation.	Suitable if no Red Flags.	
Meniere's disease	Suitable to donate gametes if no active disease.	Suitable if no Red Flags.	No identified specific genetic cause; Viral aetiology.

М	Donor's history	Family history	Comments
Meningitis	Not suitable for gamete donation in presence of active infection. Contact with meningitis – suitable to donate gametes even if on prophylactic antibiotics.	Not applicable.	
Mental Health Problems	Discuss with a designated medical officer – consider the hereditary nature of the underlying condition.	Suitable if no Red Flags.	
Mitochondrial disease	Not suitable for egg donation.	Not suitable for egg donation.	
Mitral valve prolapse	Suitable to donate sperm, although consider the potential hereditary nature of the condition. Donor's welfare needs to be taken into consideration before egg donation is considered.	Suitable if no Red Flags.	MVP can be sporadic or familial, demonstrating autosomal dominant and X-linked inheritance. Three different loci on chromosomes 16, 11 and 13 have been found to be linked to MVP, but no specific gene has been described.

Μ	Donor's history	Family history	Comments
Mpox Virus (MPX)	<ul> <li>Knowledge at the present time re MPX and the potential for transmission through gamete donation is limited. If assessing a potential donor with a history of recent/current infection with MPX or of contact with a case of MPX infection then expert microbiology advice must be sought over and above the guidance provided in this entry. As a minimum the following should be followed:</li> <li>1. Current infection – not suitable for gamete donation.</li> <li>2. Recovered from confirmed/suspected infection may be accepted (but obtain microbiology advice) if all of the following apply: <ul> <li>a. It is at least 28 days since the diagnosis of MPX, and</li> <li>b. It is at least 14 days since recovery, and the donor remains well, and</li> <li>c. It is at least 14 days since completing any antiviral or antibiotic therapy, and</li> <li>e. The donor has been discharged from all follow up, including public health surveillance and</li> <li>f. No evidence of high-risk activity.</li> </ul> </li> <li>3. Contact with an individual with MPX infection may be accepted (but obtain microbiology advice) if all the following apply: <ul> <li>a. It is more than 21 days since last contact, and</li> <li>b. The donor has been discharged from all follow up, including surveillance by public health, and</li> <li>c. The donor has been discharged from all follow up, including surveillance by public health, and</li> <li>e. The donor has completed any isolation period, and</li> <li>d. The donor has been discharged from all follow up, including surveillance by public health, and</li> </ul> </li> <li>E. The donor fulfills the criteria below regarding vaccination if applicable.</li> <li>4. Immunisation for contact/risk – donor may be accepted if all of the following apply:     <ul> <li>a. Door fulfills all the criteria in section 3 above and</li> <li>b. The course of vaccination (if more than one dose) is complete.</li> </ul> </li> <li>5. Immunisation with no known contact – individuals who have received routine vaccination with Inwanex or ano</li></ul>	Consider risk of contact	<ul> <li>Incubation period of MPX is up to 21 days. The initial symptoms are fever, myalgia, fatigue, lymphadenopathy and headache, followed by a rash starting from the primary site of infection; this rash develops into vesicles and pustules followed by scabs. Infectivity may start during initial symptoms and lasts until the rash clears and all scabs have dropped off.</li> <li>Transmission occurs through contact with infectious material from skin lesions, respiratory droplets in prolonged face-to-face contact and virus-contaminated objects such as bedding or clothing. Direct contact during sex appears to be a mode of MPX transmission.</li> <li>The entry has been updated with the new name of the virus as recommended by WHO.</li> <li>Contacts may have received vaccination, to reduce the risk of serious illness. Usually vaccination will be with Imvanex or other third generation vaccine against smallpox.</li> <li>Health care workers may also have received vaccination to protect against Mpox in the event of possible exposure to monkeypox during their work. They will be working in accordance with Infection Prevention and Control policies and with suitable Personal Protective Equipment, which if not breached means they are eligible to donate</li> </ul>

М	Donor's history	Family history	Comments
MRSA carrier	Suitable to donate unless other factors preclude donation.	Not applicable.	
Multiple Sclerosis	Not suitable for gamete donation.	Suitable if no Red Flags.	
Muscular dystrophy	Not suitable for gamete donation.	Refer to Designated Medical Officer - consider risk of hereditary transmission depending on which family members are affected.	
Myasthenia gravis	Not suitable for gamete donation.	Suitable if no Red Flags.	
Myelodysplastic svndrome	Not suitable for gamete donation.	Suitable if no Red Flags.	
Myeloproliferati ve syndrome	Not suitable for gamete donation.	Suitable if no Red Flags.	
Myocarditis	Not suitable for gamete donation if not recovered from infective cause.	Suitable if no Red Flags.	

N	Donor's history	Family history	Comments
Nephritis (Acute)	Not suitable for gamete donation in acute phase or within 12 months.	Suitable if no Red Flags.	A single attack of glomerulonephritis or pyelitis from which recovery has been complete do not necessarily disqualify the donor as it is a self-limiting disease.
Nephritis (Chronic)	Not suitable for gamete donation.	Suitable if no Red Flags.	
Neural tube defect	Not suitable for gamete donation.	Suitable if no Red Flags.	
Neurofibromatosis	Not suitable for gamete donation.	Suitable if no Red Flags.	
Neurosurgery	Not suitable for gamete donation. If the neurosurgery was carried out in the UK after 1992, providing the reason for the surgery is not itself a reason for exclusion, accept. If burr hole surgery only, accept. If it can be shown that duramater was not used during surgery and there is no evidence of malignancy, the donor may be accepted after discussion with a Designated Medical Officer.	Not applicable.	Potential risk of prion disease transmission; use of dura mater has been shown to transmit CJD in the past. Donated duramater has not been used in the UK since after 1992.

0	Donor's history	Family history	Comments
Osteoarthritis	Not suitable for gamete donation.	Suitable if no Red Flags.	The genetic bases of this disease do not follow the typical patterns of Mendelian inheritance and probably are related to alterations in multiple genes. The identification of a high number of candidate genes to confer susceptibility to the development of the osteoarthritis shows the complex nature of this disease. At the moment, the genetic mechanisms of this disease are not known.
Osteogenesis imperfecta	Not suitable for gamete donation.	Suitable if no Red Flags.	
Osteomyelitis	Refer to acute and chronic infection.	Not applicable.	
Osteoporosis	Not suitable for gamete donation.	Suitable if no Red Flags.	
Ovarian cancer	Not suitable for gamete donation.	Suitable if no Red Flags.	

Р	Donor's history	Family history	Comments
Paget's disease of bone	Not suitable for gamete donation.	Suitable if no Red Flags.	
Peptic ulcer	Not suitable for gamete donation if associated with malignant change – otherwise discuss with designated medical officer.	Not applicable.	
Perthes' disease	Suitable to donate gametes.	Suitable if no Red Flags.	Legg-Calvé-Perthes disease is usually not caused by genetic factors. The cause in these cases is unknown. In a small percentage of cases, mutations in the COL2A1 gene cause the bone abnormalities characteristic of Legg-Calvé-Perthes disease.
Pneumonia	See infection - acute.	See infection - acute.	
Polycystic Ovarian Syndrome	Suitable for gamete donation.	Not applicable.	
Polycythaemia	Not suitable for gamete donation. Refer to Haematological disease entry.	Suitable if no Red Flags.	
Porphyria	Not suitable for gamete donation.	Suitable if no Red Flags.	
Post viral fatigue syndrome	Not suitable for gamete donation if not resolved.	Not applicable.	

Ρ	Donor's history	Family history	Comments
P Prion-associated Diseases		Family history Suitable if no Red Flags.	Comments
	<ul> <li>f. Recipients of human pituitary derived extracts</li> <li>g. Since 1 January 1980 recipients of any allogeneic human tissue and/or organ</li> <li>If the donor has had two or more blood relatives develop a prion-associated disease and following genetic counselling they have been informed that they are not at risk, accept.</li> </ul>		
Prostate cancer	Not suitable for gamete donation.	Suitable if no Red Flags.	
Psoriasis	Not suitable for gamete donation.	Suitable if no Red Flags.	
Pulmonary embolism	Suitable to donate sperm only if there is no underlying haematological or other disorder that would preclude donation and the donor is not in the acute phase.	Suitable if no Red Flags.	

Р	Donor's history	Family history	Comments
Pyrexia of Unknown Origin	Not suitable for gamete donation; if resolved discuss with designated medical officer.	Not applicable.	
Pyruvate kinase deficiency	Not suitable for gamete donation.	Refer to Designated Medical Officer – consider risk of hereditary transmission depending on which family members are affected.	

Q	Donor's history	Family history	Comments
Q fever	Not suitable for gamete donation.	Not applicable.	

R	Donor's history	Family history	Comments
Rabies	Not suitable for gamete donation; If immunized post-exposure must not donate until at least 24 months post- exposure and fully cleared by treating physician. If immunisation is not post-exposure, accept gamete donation.	Not applicable.	
Raynaud's syndrome	Not suitable for gamete donation if part of a multisystem disorder.	Suitable if no Red Flags.	
Reiter's syndrome	Suitable to donate if not in active phase and no current evidence of infection.	Suitable if no Red Flags.	Reiter's syndrome is felt in part to be genetic. There are certain genetic markers that are far more frequent in patients with Reiter's syndrome than in the normal population. For example, the HLA-B27 gene is commonly seen in patients with Reiter's syndrome. Even in patients who have the genetic background that predisposes them to developing Reiter's syndrome, exposure to certain infections seem to be required to trigger the onset of the disease.
Relenza/Tamiflu	Not suitable for gamete donation if taking Relenza/Tamiflu as treatment for influenza.	Not applicable.	
	Refer to Infection Acute.		
Renal colic	Not suitable for gamete donation if symptomatic or under investigation.	Not applicable.	
Retinitis pigmentosa	Not suitable for gamete donation.	Suitable if no Red Flags.	
Rheumatic fever	Not suitable for gamete donation if in active phase/on treatment.	Suitable if no Red Flags.	

R	Donor's history	Family history	Comments
Rheumatoid arthritis	Suitable for gamete donation if mild and the only treatment is NSAIDs; most cases of severe disease will be on methotrexate, which is teratogenic. Females with rheumatoid arthritis often have low ovarian reserve and therefore may not be suitable for egg donation.	Suitable if no Red Flags.	
Ringworm	Not suitable for gamete donation if on systemic treatment.	Not applicable.	

S	Donor's history	Family history	Comments
Sarcoidosis (Acute)	Not suitable for gamete donation if not recovered or less than five years from both finishing all treatment and full recovery.	Suitable if no Red Flags.	
Sarcoidosis (Chronic)	Not suitable for gamete donation.	Suitable if no Red Flags.	
Schizophrenia	Not suitable for gamete donation.	Suitable if no Red Flags.	
Scoliosis	Not suitable for gamete donation if genetic or idiopathic; acceptable if non- hereditary e.g. due to trauma.	Suitable if no Red Flags.	
Sex worker	Not suitable for gamete donation. If 3 months or more have elapsed since the donor last received any payment for sex such as with money or drugs, accept.	Not applicable.	This assumes NAT testing in place - if not then a longer deferral period is indicated as per current guidance - at present this would be a deferral period of six months.
Sexually Transmitted Disease	Not suitable for gamete donation if less than 3 months since successfully completing treatment. If fully treated and at least 3 months from completion of treatment accept; additionally, for gonorrhea, there must be evidence of test of cure. If the donor's sexual partner had an STD – potential donor must not donate if the donor required treatment and it is less than 3 months since successfully completing the treatment or donor did not require treatment and it is less than 3 months from the last sexual contact with the infected partner. Consider whether testing of the potential donor is required;	Consider risks if sexual contact.	If relevant refer to entry for Chlamydia, Genital warts, Herpes - Genital, Syphilis, Gonorrhoea.
Sickle cell trait	specifically for gonorrhea there must be evidence of test of cure. Refer to haemoglobin disorder entry.	Suitable if no Red Flags.	
Skin disease	Suitable for gamete donation if underlying condition does not exclude donation.	Suitable if no Red Flags.	
Sleeping sickness	Not suitable for gamete donation.	Not applicable.	

S	Donor's history	Family history	Comments
Smoking	Not suitable for gamete donation if currently smoking or has smoked in the last 3 months.	Not applicable.	
Snake bite	Not suitable for gamete donation until completely recovered.	Not applicable.	
Spina bifida	Not suitable for gamete donation.	Suitable if no Red Flags.	
Splenectomy	Suitable for gamete donation if reasons for splenectomy do not preclude donation.	Suitable if no Red Flags.	
Stroke	Not suitable for gamete donation.	Suitable if no Red Flags.	
Surgery	<ul> <li>Not suitable for gamete donation if:</li> <li>surgery is for malignancy</li> <li>all wounds are not healed</li> <li>there is any infection</li> <li>normal mobility has not been regained</li> <li>less than six months from major surgery (defined as any surgical procedure resulting in an inability to return to normal daily activities for six months or more)</li> <li>less than seven days for other surgery</li> <li>requiring post-op treatment or attending hospital regularly.</li> <li>If at least four months from major surgery have passed and NAT for HCV is performed and found to be negative (as well as all other mandatory testing), accept.</li> </ul>	Not applicable.	

S	Donor's history	Family history	Comments
Syphilis	<ul> <li>Affected individual – must not donate; if fully treated in the past and confirmatory tests exclude recent infection, discuss with a Designated Medical Officer. The interpretation of syphilis testing is often difficult. The advice of an experienced microbiologist may be required before a decision on safety can be made. Consider high-risk activity.</li> <li>Current or former sexual partner of affected individual must not donate if: <ul> <li>the potential donor required treatment;</li> <li>the potential donor did not require treatment and it is less than 12 months since the infected partner has completed treatment.</li> </ul> </li> <li>If the potential donor did not require treatment and it is more than 3 months from the last sexual contact with the infected partner, accept.</li> <li>If the potential donor did not require treatment and it is more than 12 months since the infected partner and it is more than 3 months from the last sexual contact with the infected partner, accept.</li> </ul>	Consider risks if sexual contact.	Individuals with a history of syphilis infection usually remain positive for the markers of infection and interpretation of the testing available for syphilis is very difficult – in the setting of non-directed (altruistic) donation individuals with markers for syphilis infection should not be progressed to donation; in the setting of directed (known donor) donation, expert microbiology opinion will be required to ensure that treatment is considered to have been effective and careful recipient counselling and consent will be required if going ahead with donation and treatment – such donations would not be suitable for non-directed use.
Systemic Lupus Erythomatosus (SLE)	Suitable for gamete donation if mild and the treatment is not teratogenic. Females with SLE may have low ovarian reserve and therefore may not be suitable for egg donation.	Suitable if no Red Flags.	

т	Donor's history	Family history	Comments
Tetanus immunization	Not suitable for gamete donation if less than 4/52 from exposure; if non- exposed accept.	Not applicable.	
Thalassaemia major	Not suitable for gamete donation.	Suitable if no Red Flags.	
Thalassaemia trait	Refer to haemoglobin disorder entry.	Suitable if no Red Flags.	
Threadworms	Suitable for gamete donation.	Not applicable.	
Thrombocytosis	Not suitable for gamete donation. Refer to Haematological disease entry.	Suitable if no Red Flags.	
Thrombosis	Suitable for gamete donation if the underlying cause does not exclude. Refer to DVT.	Suitable if no Red Flags.	
Thrush (oral)	Not suitable for gamete donation if unexplained or related to immunodeficiency.	Not applicable.	
Thrush (vaginal)	Not suitable to donate gametes if related to immunodeficiency.	Not applicable.	
Thyroid disease	Not suitable to donate if malignant, less than six months from radioiodine treatment or if still under investigation.	Not applicable.	

т	Donor's history	Family history	Comments
Tissue and Organ Recipients	Not suitable for gamete donation if at any time has needed immunosuppression, has had dura mater transplanted, has had ocular tissue transplanted, has had xenotransplant performed or since 1 January 1980 has had any allogeneic human tissue or organ transplanted. If an allogeneic tissue or cell transplant was performed before 1 January 1980 and there is no other reason to exclude the donor, accept. If at any time autologous tissue or cells have been transplanted, accept.	Not applicable.	
Toxoplasmosis	Not suitable if current active infection with Toxoplasmosis; Historical infection of Toxoplasmosis is not a reason to defer a gamete donor.	Not applicable.	
Transfusion	An individual risk assessment needs to be carried out if the potential donor has a history of definite or probable blood component and/or blood product transfusion since 1980 in view of the potential risk of CJD transmission.* If the potential donor received or thinks they may have received a blood component and/or blood product transfusion in a country endemic for malaria or South American Trypanosomiasis, additional testing for malaria antibodies and/or T. cruzi antibodies as relevant is required (and confirmed as negative at least 4 months after last possible exposure) before the donor is accepted.	Not applicable	*Level of risk or exposure should be clarified and weighed, on an individual basis, against the expected benefit of the donation and the availability of alternative donors. The recipient should be informed of the nature of the estimated risk of vCJD transmission. Note that such individual risk assessments are only possible in the setting of a directed donation.

т	Donor's history	Family history	Comments
Tropical viruses - this includes Dengue Virus, Chikungunya Virus, Yellow Fever and Zika Virus	<ul> <li>Must not donate if:</li> <li>It is less than six months from a donor's return from a Tropical virus risk endemic area and the donor has been diagnosed with Chikungunya, Dengue, Yellow Fever or Zika infection whilst there or following their return to the UK.</li> <li>It is less than six months from a donor's return from a Tropical virus risk endemic area and the donor has either had a history of symptoms suggestive of Chikungunya, Dengue, Yellow Fever or Zika infection whilst there or following their return to the UK.</li> <li>In other cases it is less than four weeks from a donor's return from a Tropical virus risk endemic area; specifically for Zika please see below.</li> <li>All donors may be accepted six months after their return from an affected area or resolution of symptoms. This may be reduced to 4 weeks if they have had neither symptoms nor evidence of infection, but see below for Zika.</li> <li>Specifically, for the guidance on the deferral period for Zika risk, including the potential risk of transmission through intercourse without a personal history of travel, please refer to the regularly updated guidance at <u>People Trying to Conceive   CDC</u> which provides guidance on deferral period depending on the travel history of both the donor and/or their sexual partner</li> <li>Please refer to the Geographical Disease Risk Index for a list of countries where the Tropical viruses are considered a travel-related risk. <a href="https://www.transfusionguidelines.org/dsg/gdri">https://www.transfusionguidelines.org/dsg/gdri</a></li> </ul>	Not applicable.	
Trypanosomiasis	Known infection: Not suitable for gamete donation. Must not donate if donor or donor's mother was born in South America or Central America (including Southern Mexico) or if donor has had a transfusion in South America or Central America (including Mexico) or has lived and/or worked in rural subsistence farming communities in these countries for a continuous period of four weeks or more.	If the donor's mother is born in South America or Central America (including Southern Mexico) donor should be tested for T. cruzi before donating gametes.	If at least four months from the date of the last exposure and a validated test for T. cruzi antibody is negative donor can be accepted.

т	Donor's history	Family history	Comments
Tuberculosis	Not suitable for gamete donation if current infection, or still under follow up, or less than 2 years since successful treatment or a diagnosis of latent TB in the last 2 years. Note if the donor has a history of TB (active or latent) that has been treated, with the treatment being finished more than 2 years prior to donation, a full risk assessment still needs to be carried out before deciding whether donation can be progressed – this will require detail of site of infection, treatment given and will require input by microbiology experts. Contact with TB - must not donate until screened and cleared.	Not applicable although consider potential exposure of donor.	TB can affect the genital tract. It is difficult to confirm that treatment for TB has eradicated infection – careful assessment is required before progressing donation from donors with a history of either active or latent TB. As a precaution no donors must be progressed if treatment and/or diagnosis was in the 2 years prior to donation; if successful treatment was more than 2 years prior to donation then a full risk assessment with input from microbiology experts is still required before progressing donation.
Turner's syndrome	Not suitable for gamete donation.	Refer to Designated Medical Officer.	

U	Donor's history	Family history	Comments
Ulcer (peptic)	Suitable for gamete donation unless underlying condition/medication renders donor not suitable for gamete donation.	Not applicable.	

ν	Donor's history	Family history	Comments
Vasculitis	Not suitable for gamete donation.	Suitable if no Red Flags.	
Viral haemorrhagic fever	<ul> <li>If donor has ever been infected with VHF, must not donate.</li> <li>If donor travelled to a VHF endemic country or had contact with VHF must not donate if: <ul> <li>was present in a VHF endemic area during an active outbreak</li> <li>under investigation for VHF</li> <li>has been in contact with an individual who was present in an area during an active outbreak</li> <li>was in contact with an individual infected with, or was under investigation for, VHF</li> <li>less than six months after return to the UK from an endemic area when there was no active outbreak</li> </ul> </li> <li>Donor would be suitable to donate if: <ul> <li>more than 6 months after return to UK from a VHF endemic area when there was no active outbreak at the time of the visit</li> </ul> </li> <li>the individual or the contact person under investigation for VHF had VHF infection excluded as a diagnosis using a validated assay.</li> <li>If donor is the sexual partner of an individual affected by VHF – must not donate if the donor has had sex with an individual who has been diagnosed with a VHF at any time before their last sexual contact.</li> </ul> <li>Please refer to the Geographical Disease Risk Index to check for countries where VHF e.g. Ebola are endemic.</li> <li>https://www.transfusionquidelines.org/dsg/gdri</li>	Not applicable, although consider contact with donor.	There is evidence of persistent virus in individuals who recover from several forms of VHF and asymptomatic individuals may be able to transmit the virus to others.
Von Willebrand's disease	Not suitable for gamete donation.	Suitable if no Red Flags.	

w	Donor's history	Family history	Comments
Warts	Suitable to donate if there are no viral infections/high risk behaviours.	Not applicable.	If relevant refer to Genital Warts
West Nile Virus	<ul> <li>Not suitable for gamete donation if: <ul> <li>less than six months from donor's return from WNV endemic area and donor has been diagnosed with WNV whist there or on return.</li> <li>less than six months from the donor's return from WNV endemic area and the donor has either had a history of symptoms suggestive of WNV whist there or within 28 days of their return.</li> </ul> </li> <li>If donor was well while abroad and within four weeks of return to the UK can accept.</li> <li>If donor was well while abroad and less than four weeks since return to the UK can accept if WNV NAT testing is negative.</li> <li>Donor with symptoms following travel abroad that may have been secondary to WNV may be accepted at less than six months from the symptoms if WNV NAT testing is negative – discuss with designated medical officer.</li> <li>Please refer to Geographical Disease Risk Index.</li> </ul>	Not applicable.	
Wilson's disease	Not suitable for gamete donation.	Refer to Designated Medical Officer – consider risk of hereditary transmission depending on which family members are affected.	

x	Donor's history	Family history	Comments
Xenotransplantation	Not suitable for gamete donation if material from a living non-human animal source has been directly or indirectly in contact with the donor's blood supply. This does not include animal bites.	Not applicable.	Any procedure that involves the transplantation, implantation or infusion into a human recipient of either live cells, tissues or organs from non human animal source or human body fluids, cells, tissues, or organs that have had ex-vivo contact with live, non human animal cells, tissues or organs.
XMRV (Xenotropic murine leukemia virus-related virus)	Not suitable for gamete donation.	Not applicable.	

Y	Donor's history	Family history	Comments
Yaws	Not suitable for gamete donation.	Not applicable.	

Z	Donor's history	Family history	Comments
	Please refer to Tropical Virus entry and also refer to the most up to date Zika virus guidance from HFEA.	Consider contact with donor.	

## **Abbreviations:**

- CJD Creutzfeldt-Jakob disease
- CIN Cervical Intraepithelial Neoplasia
- CNS Central Nervous System
- DVT Deep Vein Thrombosis
- GBS Guillian Barré Syndrome
- HIV Human Immunodeficiency Virus
- HFEA Human Fertilisation Embryology Authority
- HBV Hepatitis B virus
- HCV Hepatitis C virus
- HEV Hepatitis E virus
- HTLV Human T-cell Lymphotropic Virus
- MS Multiple Sclerosis
- NAT Nucleic Acid Testing
- VHF Viral Haemorrhagic Fever
- WNV West Nile Virus

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