DukeMedicine
Division of Cellular Therapy

ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

DOCUMENT NUMBER: APBMT-COMM-001 JA1

DOCUMENT TITLE:
Medical History Exclusion Criteria JA1

DOCUMENT NOTES:

Document Information

Revision: 09	**Vault:** APBMT-Common-rel
Status: Release	**Document Type:** APBMT

Date Information

Creation Date: 14 May 2020	**Release Date:** 01 Mar 2021
Effective Date: 01 Mar 2021	**Expiration Date:**

Control Information

Author: MC363	**Owner:** MC363
Previous Number: APBMT-COMM-006 Rev 08	**Change Number:** APBMT-CCR-180

APBMT-COMM-001 JA 1
MEDICAL HISTORY EXCLUSION CRITERIA

Donor Health History Exclusion Criteria

Instructions:

- **Use this job aid with *APBMT-COMM-001 FRM 3 Donor Health History Questionnaire.***
- **The Donor Center Staff will document how the form was administered, if an interpreter was required, if an arm inspection was needed and who performed the inspection, and answer any questions the donor may have as needed.**
- **The Donor Center Staff will print and sign the *APBMT-COMM-001 FRM 3 Donor Health History Questionnaire.***
- **All exclusion information and responses will be evaluated by the Medical Director/designee prior to donor's collection for donor/recipient safety.**
- **The Medical Director/designee will sign the *APBMT-COMM-001 FRM 3 Donor Health History Questionnaire* if he/she agrees with the reviewed responses and approves the collection.**

Question:	Responses/Exclusion Criteria:
1. Have you read the educational materials provided to you?	Yes: Accept No: Give the donor the educational material (Auto/Allo/NMDP Information Handouts, Reference A, B, and C information) to read, or review with them if unable to read.
2. Are you in good health?	Yes: Accept No: Evaluate for medical conditions. Evaluate for donor/recipient safety issues and refer to Medical Director/designee for acceptance.
3. Are you currently taking any other medication, including antibiotics, over the counter medications, vitamins, herbal products or investigational drugs? ***Donor to supply list of medication and reason for taking**	Yes: Review meds and evaluate underlying condition requiring medication. Evaluate what the donor is taking and why. Evaluate for donor/recipient safety issues and refer to Medical Director/designee for acceptance. *Example: Is the donor taking chemo, cardiac, immunosuppressive drugs or injecting insulin? These are a reason for deferral.* No: Accept
4. Are you now, or have you EVER, taken any of the medications on the Medication Deferral List? ***Refer to reference A for the "Medication Deferral List"**	Yes: Defer donation in accordance with the deferral periods listed on the Medication Deferral List: No: Accept
5. Do you have any food, drug, latex or environmental allergies?	Yes: Evaluate for mild or severe (anaphylactic) allergy. Evaluate for donor safety issues and refer to Medical Director/designee for acceptance. No: Accept
6. Do you have an autoimmune disorder such as diabetes, psoriasis, Crohn's, Hashimoto's, MS, Lupus, Raynaud's, or a condition causing inflammation in the eye such as iritis or episcleritis?	Yes: Some cGSF may worsen an autoimmune condition. Donor risk. Evaluate autoimmune disorder and refer to Medical director/designee for acceptance or deferral from PBSC donation. Harvest and Non-mobilized donation is acceptable. *Example of deferral: Lupus, Rheumatiod arthritis.* No: Accept
7. In the past 12 months, have you needed treatment in an emergency room, been hospitalized, or had surgery?	Yes: Evaluate the reason for treatment. Evaluate for donor/recipient safety issues and refer to Medical Director/designee for acceptance.

APBMT-COMM-001 JA 1
MEDICAL HISTORY EXCLUSION CRITERIA

Donor Health History Exclusion Criteria

Question:	Responses/Exclusion Criteria:
	Example: Major vs. minor trauma. Recovery status (fully vs. still recovering). No: Accept
8. In the past 12 months, have you received a tissue transplant such as bone or cornea?	Yes: Evaluate due to potential exposure risk to infectious diseases such as HIV or hepatitis. Refer to Medical Director/designee for acceptance. No: Accept
9. Have you ever had a blood transfusion from a source other than your own blood either domestically or internationally? ***Donor will document when and where this occurred.**	Yes: Evaluate due to risk of blood product recipient developing antibodies from exposure to foreign proteins. Refer to Medical Director/designee for acceptance. No: Accept
10. Have you ever received an organ, bone marrow, or stem cell transplant or donated an organ, such as a kidney?	Yes: **Recipient**: Organ or stem cell **recipient** is a deferral. **Donor**: Evaluate **donor** of organ or stem cells for organ function and recovery from donation. Refer to Medical Director/designee for acceptance. No: Accept
11. Have you or any of your blood relatives ever had problems with general or regional anesthesia such as an epidural or spinal block?	Yes: Evaluate any anesthesia complications. Refer to Medical Director/designee for acceptance. *Example: Malignant hyperthermia is a deferral.* Donor may be considered for PBSC. No: Accept
12. Have you ever had neck, back, hip or spine problems? ***Donor will describe current status, treatments, limitations and any related surgeries. Also, include their current pain level.**	Yes: Evaluate current status. Baseline pain status. May increase the potential for post-collection complications of marrow donors. PBSC donors must be able to tolerate sitting/lying for long periods of time for collection. Refer to Medical Director/designee for acceptance. No: Accept
13. Have you ever had breathing problems, including asthma, COPD, sleep apnea or shortness of breath?	Yes: Evaluate underlying cause for donor safety issues. Increased medical risk to marrow donors due to anesthesia. Refer to Medical Director/designee for acceptance. No: Accept
14. Have you ever had a heart attack, heart-related chest pains, heart disease, heart surgery or been diagnoses with atrial fibrillation or any other abnormal heart rhythm?	Yes: Evaluate for donor safety issues and refer to Medical Director/designee for acceptance. *Example of deferrals: TIA; Angina diagnosis; Cardiomyopathy; CAD; MI; Pacemaker; CABG; Stent; Aneurism.* No: Accept
15. Have you ever had Sickle Cell Disease or Thalassemia?	Yes: Defer No: Accept
16. Have you ever had cancer? ***Donor will describe type, stage, treatment, and any recurrence.**	Yes: Evaluate for type of cancer and treatment. Refer to Medical Director/designee for acceptance. No: Accept

APBMT-COMM-001 JA 1
MEDICAL HISTORY EXCLUSION CRITERIA

Donor Health History Exclusion Criteria

Question:	Responses/Exclusion Criteria:
17. Have you ever had a parasitic blood disease such as Chagas' disease or Babesiosis?	Yes: Defer if history of diagnosis with Chagas' or Babesiosis. Evaluate for negative confirmatory test and refer to Medical Director/designee for acceptance. No: Accept
18. Have you ever had a brain injury or head trauma, such as a concussion, skull fracture or traumatic brain injury (also called TBI.) ***Donor will describe each injury, dates, symptoms or any loss of consciousness.**	Yes: Evaluate for donor safety issues and refer to Medical Director/designee for acceptance. See NMDP Assessment tool at work up for Brain injury algorithm. No: Accept
19. Have you ever had a stroke, a blood clot (also called a deep vein thrombosis or DVT) or do you have a bleeding or clotting disorder such as Hemophilia or Factor Five Leiden?	Yes: Defer donor with history of DVT, Pulmonary embolism, stroke per NMDP. Defer if having hemophilia, thrombocytopenia (platelet count < 100), history of ITP or having received human derived clotting factors (Risk factor for HIV/Hepatitis B and C). A donor who received clotting factors once to treat an acute bleeding event more than 12 months ago may be eligible to donate. Evaluate for donor safety issues and refer to Medical Director/designee for acceptance. No: Accept
20. Is there any other **past or present** health information that we have not discussed, such as a past surgery, chronic medical condition, serious injury and mental health diagnosis?	Yes: Open question to provide donor opportunity to disclose any additional pertinent information. Evaluate response. Refer to Medical Director/designee for acceptance. No: Accept
21. Has your child eaten any foods in the past 72 hours (3 days) that the recipient of your child's cells is allergic to? ***Only used for pediatric related donor setting**	Yes: The product would require and/or need to be washed and the recipient would require and/or need extra premeds before infusion. Evaluate for recipient safety. No: Accept N/A: Adult donor
22. In the past 4 weeks have you had any vaccinations (other than smallpox) or any kind of shot?	Yes: Evaluate vaccinations or shots the donor has received. There is a remote possibility the immunocompromised patient can be exposed to the involved disease. If live, attenuated vaccines were administered, delay collection by 2-4 weeks: Delay collection 2 weeks after receiving: measles (rubella), mumps, oral polio, yellow fever. Delay collection 4 weeks after receiving: German measles (rubella). Refer to Medical Director/designee for acceptance. No: Accept
23. Are you planning to receive any vaccinations (including smallpox) or shots?	Yes: Evaluate the vaccinations the donor is scheduled to receive. Refer to Medical Director/designee for acceptance. Counsel donor to delay vaccinations until after donation if possible.

APBMT-COMM-001 JA 1
MEDICAL HISTORY EXCLUSION CRITERIA

Donor Health History Exclusion Criteria

Question:	Responses/Exclusion Criteria:
	If live, attenuated vaccines: German measles (rubella), measles (rubella), mumps, oral polio, yellow fever are to be administered, there will be a 2-4 week delay for collection. No: Accept
24. In the past 8 weeks, have you received a smallpox vaccine? ***Donor who answers "Yes" is required to answer questions #24A- #24C**	Yes: Evaluate if < 8 weeks for full recovery and any vaccination complications (skin rash/sores). This is a live virus vaccine that can cause complications in an immunocompromised patient. Refer to Medical Director/designee for acceptance. No: Accept
24A. When did you receive the vaccination?	Evaluate if < 8 weeks. See questions #28.
24B. Did the scab fall off your skin by itself	Yes: No complications defer until vaccination scab has separated spontaneously, or for 21 days post-vaccination, which is the later date. No Evaluate for complications. Defer the donor for two months after vaccination.
24C. Did you have any illness or complications due to the vaccination such as an eye infection or a rash, an allergic reaction, or sores beside those from the vaccination site?	Yes: Evaluate the illness or complication. Defer the donor until 14 days after all complications have completely resolved. No: Accept: No complications defer until vaccination scab has separated spontaneously, or for 21 days post-vaccination, which is the later date.
25. Have you had close contact with the vaccination site (such as touching the vaccination/scab or bandages, or handling the clothes, towels or bedding) of anyone who has received the smallpox vaccine in the past 3 months? ***If donor answered "Yes", questions #25A-#25C is required**	Yes: Evaluate for close contact (including intimacy) within the past 3 months with anyone who has received the vaccine. This is a live virus vaccine that can cause complications in an immunocompromised patient. Refer to Medical Director/designee for acceptance. No: Accept
25A. When did the person receive the vaccination? ***Donor to provide Date.**	Evaluate if < 3 months. See questions # 29.
25B. When was the close contact? ***Donor to provide Date.**	Evaluate if < 3 months. See questions #29 and #29A.
25C. Have you had any new skin rash, sores, or an eye infection since the time of the contact?	Yes: Question the donor regarding the loss of the scab, and examine the skin. If no scab is present, FDA does not recommend deferral: A living donor if scab spontaneously separated; or after three months from the date of vaccination of the vaccine recipient, a living donor whose scab was otherwise removed. If a scab is present, the donor should be deferred until the scab spontaneously separates. No: Accept

APBMT-COMM-001 JA 1
MEDICAL HISTORY EXCLUSION CRITERIA

Donor Health History Exclusion Criteria

Question:	Responses/Exclusion Criteria:
26. In the past 3 years, have you had malaria?	Yes: Evaluate when malaria was diagnosed. Can be transmitted by blood products. Refer to Medical Director/designee for acceptance. REFER TO THE CDC website: www.cdc.gov for Malarial areas. No: Accept
27. In the past 3 years, have you **lived** (12 months or more) outside the United States or Canada? ***Donor will list where, when, and for how long and if they took anti-malarial medications.**	Yes: Evaluate where residency was in the past 3 years. Possible risk for malaria. Can be transmitted by blood products. Refer to Medical Director/designee for acceptance REFER TO THE CDC website: www.cdc.gov (Travelers Health TAB) Clinical tools and resources. No: Accept
28. In the past 12 months, have you **traveled** (less than 12 months) outside the United States or Canada? ***Donor will list where, when, and for how long and if they took anti-malarial medications.**	Yes: Evaluate where donor has traveled. Possible exposure risk to Ebola if travel to West Africa: Guinea, Liberia, and Sierra Leone. Possible risk for malaria. Can be transmitted by blood products. Refer to Medical Director/designee for acceptance. REFER TO THE CDC website: www.cdc.gov (Travelers Health TAB) Clinical tools and resources. No: Accept
29. In the past 120 days (4 months), have you been suspected of having or been diagnosed with West Nile Virus? ***Donors that answer "Yes" are required to answer #27A**	Yes: The Donor Referral Panel-Viromed will test for West Nile Virus. Since this can be transmitted through stem cell donation, evaluate for symptoms of a fever, headache, eye pain, body aches, a generalized skin rash, or swollen lymph nodes. Refer to Medical Director/designee for acceptance. No: Accept
29A. When were you told this? ***Donor required to supply the date they were told this**	Evaluate if < 120 days (4 months). Evaluate any residual impairment. The FDA recommends that you defer a potential donor with a medical diagnosis or suspicion of WNV infection (based on symptoms and/or laboratory results) for 120 days following diagnosis or onset of illness, whichever is later. At your discretion, you may reenter such donors after the 120 day deferral period.
30. Have you been diagnosed with Creutzfeldt-Jakob disease (CJD) or variant CJD, or do you have a degenerative neurological condition such as dementia where the cause has not been identified? ***If donor answered "Yes", question #30A-#30B is required**	Yes: Evaluate for temporary or progressive condition. If Guillian-Barre, accept if fully recovered. Defer if diagnosed with CJD/VCJD or degenerative neurological disease of undiagnosed origin. Refer to Medical Director/designee for acceptance. No: Accept
30A: Have you ever had a dura mater (or brain covering) transplant for a head or brain injury?	Yes: Evaluate response for underlying condition. Defer if residual neurological complication due to brain injury is significant. There is a risk that recipients of dura mater grafts from cadaver donors may develop CJD. This is an increased risk to the stem cell recipient. Refer to Medical Director/designee for acceptance. No: Accept

APBMT-COMM-001 JA 1
MEDICAL HISTORY EXCLUSION CRITERIA

Donor Health History Exclusion Criteria

Question:	Responses/Exclusion Criteria:
30B: Have you ever received growth hormone made from human pituitary glands?	Yes: Evaluate why and when (year) growth hormone was received. Prior to 1985, the growth hormone was obtained from cadavers, and has the risk of transmitting CJD. After 1985, a synthetic growth hormone was used in the USA. Defer if unsure of when growth hormone was administered. Refer to Medical Director/designee for acceptance. No: Accept
31. 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: Evaluate response. Defer if any 1st degree relative has been diagnosed with CJD. Refer to Medical Director/designee for acceptance. No: Accept
32. 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: Hepatitis A: Eligible Hepatitis B: Defer Hepatitis C: Defer. No: Accept
33. In the past 12 months, have you had a tattoo? ***Donor to provide date applied, any signs of infection, and note if performed in licensed establishment**	Yes: Risk of HIV/Hepatitis B and C exposure. Evaluate for signs/symptoms of infection post tattoo. Defer if not applied in licensed facility, applied < 12months ago. No: Accept
34. In the past 12 months, have you had an ear, skin or body piercing using shared instruments or needles? ***Donor to provide date applied, any signs of infection, and note if performed in licensed establishment**	Yes: Risk of HIV/Hepatitis B and C exposure. Evaluate for signs/symptoms of infection post piercing. Accept if >12 months since piercing, or < 12 months from piercing and sterile needles/instruments were used. No: Accept
35. In the past 12 months, have you had an accidental needle stick or come in contact with someone else's blood through an open wound, non-intact skin (Example: a cut or sore), or mucus membranes (Example: into your eye or mouth)?	Yes: Risk of HIV/Hepatitis B and C exposure. Evaluate for signs/symptoms of infection if < 12 months from exposure. Accept if > 12months from exposure. No: Accept
36. In the past 12 months, have you been held in jail, prison, juvenile detention, or lockup for more than 72 continuous hours?	Yes: Risk of HIV/Hepatitis B and C exposure Evaluate for signs/symptoms of infection if < 12 months. No: Accept
37. Have you traveled to Africa in the past 2 months?	Yes: Risk factor for HIV group O, Zika, Ebola virus No: Accept

APBMT-COMM-001 JA 1
MEDICAL HISTORY EXCLUSION CRITERIA

Donor Health History Exclusion Criteria

Question:	Responses/Exclusion Criteria:
38. Have you been exposed to anyone with Ebola virus or anyone that has been exposed to the Ebola virus?	Yes: Defer. Refer to the CDC.Gov website to review Ebola outbreak distribution map. Indefinite deferral of a donor with a history of Ebola virus infection or disease. Eight week deferral from the date of his/her departure a donor who has resident or travelled to an area of wide spread transmission, last close contact by a person with confirmed Ebola virus infection or disease, those that have been contact by government regarding potential exposure. No: Accept
39. Since 1977, were you born in or have you lived in Africa ***If donor answers "Yes", # 39A- #39B are required.**	Yes: Risk factor for HIV group O No: Accept
39A: Was it Benin, Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, Nigeria Senegal, Togo or Zambia?	Yes: Risk factor for HIV group O No: Accept
39B: Did you receive a blood transfusion or medical treatment with a blood product while there?	Yes: Risk factor for HIV group O. No: Accept
40. Since 1980, have you ever lived in or traveled to Europe? (See reference B for a list of the countries in Europe) *** If donor answers "Yes", #40A-#40D is required.**	Yes: Risk of new variant CJD. Identified in 1996 in the UK. Defer if time spent in UK or European countries during listed years. Defer if ever received a blood transfusion while in the UK or France during listed years. Consult current FDA guidelines for CJD risks areas and deferral areas (also see question 27) at the following link: Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) (See Appendix 5). Review with medical director for approval. If in deferral area for infectious diseases, exclude. If no, eligible to donate. No: Accept
40A. From 1980 through 1996, did you spend time that adds up to three (3) months or more in the United Kingdom (UK)? (England, Northern Ireland, Scotland, Wales, Isle of Man, Channel Islands, Gibraltar, or Falkland Islands)	Yes: Same as Above No: Accept
40B. Since 1980, did you receive a transfusion of blood or blood components while in the UK or France?	Yes: Same as Above No: Accept
40C. Since 1980, have you spent time that adds up to 5 years or more in Europe, including time spent in the UK from 1980-1996?	Yes: Same as Above No: Accept

APBMT-COMM-001 JA 1
MEDICAL HISTORY EXCLUSION CRITERIA

Donor Health History Exclusion Criteria

Question:	Responses/Exclusion Criteria:
40D.From 1980 through 1996, were you a member of the U.S. military, a civilian military employee, or a dependent of a member of the U.S. military? ***If donor answers "Yes", #40D [a] and #40D [b]**	Yes: NO LONGER FDA required: (Accept) 2020 Guidance Update No: Accept
40 [D1]: Did you spend a total of 6 months or more between 1980 and 1990 at a military base in any of the following countries: Belgium, Germany, and Netherlands?	Yes: Accept (Comparison of Recommendations in 2016 Guidance and 2020 Guidance) No: Accept
40 [D2]: Did you spend a total of 6 months or more between 1980 and 1996 at a military base in any of the following countries: Greece, Italy, Portugal, Spain or Turkey?	Yes: Accept (Comparison of Recommendations in 2016 Guidance and 2020 Guidance) No: Accept
41. Have you had or anyone in your household had a medical diagnosis of ZIKA virus in the past 6 months?	The ZIKA Virus is primarily transmitted to humans through a mosquito bite. Many times, infected individuals are asymptomatic. Symptoms experienced are usually mild, and may occur between 2-12 days after exposure. These include low grade fever, arthralgias, myalgia, headache, retro-ocular headaches, non-purulent conjunctivitis, or cutaneous maculopapular rash. The period of viremia generally last 7 days. The ZIKA virus can also be transmitted to females during sexual contact with males. There has been an association of microcephaly in infants born to women infected with the ZIKA virus during the first trimester of pregnancy. Information where ZIKA virus has been diagnosed is on the CDC website: https://www.cdc.gov/zika/areasatrisk.html Consult current CDC guidelines for Zika risks areas and deferral areas at the following link: https://www.cdc.gov/zika/areasatrisk.html . Review with medical director for approval. If in deferral area for infectious diseases, exclude. If no, eligible to donate. Yes: Consult Medical Director No: Accept
42. Have you or anyone in your household resided in, or traveled to an area with an increased risk for ZIKA virus transmission within the past 6 months?	Yes: Same as Above No: Accept
43. Are you sexually active? ***If donor answers "Yes", #44-#48 is for female donors and #49 is for male donors. #50-#62 is required by all.**	Follow-up information

APBMT-COMM-001 JA 1
MEDICAL HISTORY EXCLUSION CRITERIA

Donor Health History Exclusion Criteria

Question:	Responses/Exclusion Criteria:
44. Female Donor: How many times have you been pregnant?	Yes: Evaluate due to risk of donor developing antibodies from their infant's blood. Refer to Medical Director/designee for acceptance. No and N/A: Accept
45. Female donor: In the past 6 weeks, have you been pregnant or are you now pregnant?	Yes: Current pregnancy is a deferral. Evaluate recent pregnancy for recovery status and refer to Medical Director/designee for acceptance. Breastfeeding: Interrupt during cGSF administration, may resume 2 days following last dose of CGSF. Do not collect breast milk while receiving cGSF. No: Accept
46. Female Donor: Have you had any health problems associated with or caused by pregnancy?	Yes: Evaluate complications for donor safety issues. Refer to Medical Director/designee for acceptance. Example: Gestational diabetes, hypertension. No: Accept
47. Female donor: Do you plan to or is there any chance that you will become pregnant within the next 6 months?	Yes: Evaluate for future donation availability. Pregnancy is a deferral. No: Accept
48. 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: Risk of HIV/Hepatitis B exposure. Evaluate for signs/symptoms of infection if < 12 months. No: Accept
49. Male donor: In the past 5 years, have you had sex, even once, with another male?	Yes: Risk of HIV/Hepatitis B exposure. Evaluate for signs/symptoms of infection if < 5 years since contact. No: Accept
50. All Sexually Active donors: In the past 5 years, have you exchanged money, drugs, or other payment in exchange for sex?	Yes: Risk of HIV/Hepatitis B and C exposure. Evaluate for signs/symptoms of infection if < 5 years from last encounter. No: Accept
51. 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: Risk of HIV/Hepatitis B and C exposure. Evaluate for signs/symptoms of infection if < 5 years from last encounter. No: Accept
52. Have you had sex with a person who is known to have had a medical diagnosis of ZIKA virus, resided in, or traveled to, an area with active ZIKA virus transmission within the 6 months?	The ZIKA Virus is primarily transmitted to humans through a mosquito bite. Many times, infected individuals are asymptomatic. Symptoms experienced are usually mild, and may occur between 2-12 days after exposure. These include low grade fever, arthralgias, myalgia, headache, retro-ocular headaches, non-purulent conjunctivitis, or cutaneous maculopapular rash. The period of viremia generally last 7 days. The ZIKA virus can also be transmitted to females during sexual contact with males. There has been an association of microcephaly in

APBMT-COMM-001 JA 1
MEDICAL HISTORY EXCLUSION CRITERIA

Donor Health History Exclusion Criteria

Question:	Responses/Exclusion Criteria:
	infants born to women infected with the ZIKA virus during the first trimester of pregnancy. Information where ZIKA virus has been diagnosed is on the CDC website: https://www.cdc.gov/zika/areasatrisk.html Consult current CDC guidelines for Zika risks areas and deferral areas at the following link: https://www.cdc.gov/zika/areasatrisk.html . Review with medical director for approval. If in deferral area for infectious diseases, exclude. If no, eligible to donate. Yes: Consult Medical Director No: Accept
53. Have you, any of your sexual partners, or any members of your household ever had a xenotransplant (tissues from an animal) or a medical procedure that involved being exposed to live cells, tissues, or organs from an animal?	Yes: Defer if ever having a Xeno transplant: includes any transplanted organ, porcine (pig) heart valve, from a nonhuman animal source. Defer if the donor had potential to be exposed to blood salvia, or body fluids from transplant recipient. No: Accept
54. Have you ever tested positive for syphilis, including screening tests, or ever been treated for syphilis with in the last 12 months?	Yes: FDA does not recommend deferral of donor if evidence is presented that the treatment occurred more than 12 months ago and was successful. No: Accept
55. Have you ever tested positive for HIV or do you have AIDS, including screening tests.	Yes: Defer if diagnosed with AIDS/HIV or has confirmed positive testing for all allogeneic donors. Evaluate if history of positive screening test with negative confirmatory tests for HIV. The Donor Referral Panel- Viromed will test for HIV 1/2/0. Refer to Medical Director/designee for acceptance. No: Accept
56. Do you have any of the following? • unexplained weight loss, night sweats, or persistent diarrhea • unexplained persistent cough or shortness of breath • unexplained persistent white spots or unusual sores in the mouth • unexplained temperature higher than 100.5°F (38.0°C) for more than 10 days • blue or purple spots on or under the skin or mucus membranes • lumps in the neck, armpits, or groin lasting longer than one (1) month	Yes: These symptoms describe the possible infection of HIV. Evaluate the unexplained and persistent responses. Defer if symptoms cannot be explained. (Diet=weight loss/Menopause=night sweats/Temporary= fever, diarrhea) Refer to Medical Director/designee for acceptance. No: Accept

APBMT-COMM-001 JA 1
MEDICAL HISTORY EXCLUSION CRITERIA

Donor Health History Exclusion Criteria

Question:	Responses/Exclusion Criteria:
57. Have you ever tested positive for HTLV (Human T-Lymphotropic virus), including screening tests?	Yes: Defer if diagnosed with HTLV-I or HTLV-II. Can be transmitted in donor cells. HTLV risks include: IV drug use, multiple sex partners, genital ulcers, history of syphilis. The Donor Referral Panel-Viromed will test for HTLV I/II. No: Accept
58. In the past 12 months, have you lived with or had sexual contact with anyone having yellow jaundice, hepatitis, or have you received the Hepatitis B Immune Globulin (HBIG)?	Yes: Risk of Hepatitis exposure. Evaluate for signs/symptoms of infection if <12 months since exposure. No: Accept
59. 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: Risk of HIV/Hepatitis B and C exposure. Evaluate exposure if <12 months. No: Accept
60. 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 exchanged money, drugs, or other payment in exchange for sex in the past 5 years?	Yes: Risk of HIV/Hepatitis B and C exposure. Evaluate exposure if <12 months. No: Accept
61. In the past 12 months, have you had sex, even once, with anyone who has taken human-derived clotting factors in the past 5 years?	Yes: Risk of HIV/Hepatitis B and C exposure. Evaluate for signs/symptoms of infection if <12 months. No: Accept
62. In the past 12 months, have you had sex, even once, with anyone who has AIDS or tested positive for the AIDS virus?	Yes: Risk of HIV/Hepatitis B and C exposure. Evaluate for signs/symptoms of infection if <12 months. No: Accept
63. Do you have any additional questions regarding this form or the donation process? **If "Yes", list any questions you may have in the remarks section and these will be reviewed with a member of your team.**	

Signature Manifest

Document Number: APBMT-COMM-001 JA1 **Revision:** 09
Title: Medical History Exclusion Criteria JA1
Effective Date: 01 Mar 2021

All dates and times are in Eastern Time.

APBMT-COMM-001 JA1 Medical History Exclusion Criteria

Author

Name/Signature	Title	Date	Meaning/Reason
Mary Beth Christen (MC363)		18 Sep 2020, 02:41:47 PM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
Nelson Chao (CHAO0002)		18 Sep 2020, 02:50:00 PM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		18 Sep 2020, 04:32:20 PM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Bing Shen (BS76)		19 Nov 2020, 06:07:13 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Betsy Jordan (BJ42)		04 Feb 2021, 01:24:03 PM	Approved