DukeMedicine
Division of Cellular Therapy

ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

DOCUMENT NUMBER: APBMT-COMM-001 FRM3

DOCUMENT TITLE:
Donor Health History Questionnaire FRM3

DOCUMENT NOTES:

Document Information

Revision: 02	**Vault:** APBMT-Common-rel
Status: Release	**Document Type:** APBMT

Date Information

Creation Date: 20 Jul 2020	**Release Date:** 01 Mar 2021
Effective Date: 01 Mar 2021	**Expiration Date:**

Control Information

Author: MC363	**Owner:** MOORE171
Previous Number: APBMT-COMM-001 FRM3 Re	**Change Number:** APBMT-CCR-178

Form
M0345

APBMT-COMM-001 FRM3
DONOR HEALTH HISTORY QUESTIONNAIRE

Date: ___/___/___

Name:		Date of Birth: / /	History Number:
Gender: ☐Male ☐Female	Home Phone: ☐N/A	Cell Phone:	

Height: (Peds) cm/in	Weight: (Peds) kg/lbs	Temp: (Peds) C/F	Pulse: (Peds)	HCT: (Peds)	HBG: (Peds)

Instructions:

- **Adult and/or Pediatric (Peds) Donors:**
  - **If you are the donor, each question should be addressed from your perspective-"have you…?"**
  - **If you are the parent or guardian of the donor, each question should be answered from the perspective of your child- "has your child…?"**
- **Mark your response clearly as "YES", "NO", or "N/A", if applicable.**
- **For all questions answered with a "YES", Please respond in Remarks Section.**
- **If you have any questions, please discuss them with your donor center staff.**

Section 1: General Assessment and Donor Safety	YES	NO	Remarks
1. Have you read the educational materials provided to you?	☐	☐	
2. Are you in good health?	☐	☐	
3. Are you currently taking any medication, including antibiotics, over the counter medications, vitamins, herbal products, or investigational drugs? **If yes, please list medications and reason for taking**	☐	☐	
4. Are you now, or have you EVER, taken any of the medications on the Medication Deferral List? **See reference A for the "Medication Deferral List"**	☐	☐	
5. Do you have any food, drug, latex, or environmental allergies?	☐	☐	
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?	☐	☐	
7. In the past 12 months, have you needed treatment in an emergency room, been hospitalized, or had surgery?	☐	☐	
8. In the past 12 months, have you received a tissue transplant such as bone or cornea?	☐	☐	
9. Have you ever had a blood transfusion from a source other than your own blood either domestically or internationally? **If Yes, document when and where this occurred.**	☐	☐	
10. Have you ever received an organ, bone marrow, or stem cell transplant or donated an organ, such as a kidney?	☐	☐	
11. Have you or any of your blood relatives ever had problems with a general or regional anesthesia such as an epidural or spinal block?	☐	☐	
12. Have you ever had neck, back, hip, or spine problems? **If yes, describe your current status, treatments, limitations, and any related surgeries. Include your current pain level**	☐	☐	
13. Have you ever had breathing problems, including asthma, COPD, sleep apnea, or shortness of breath?	☐	☐	

Form M0345

DUKE UNIVERSITY HEALTH SYSTEM

History #:_____

	YES	NO	Remarks
14. Have you ever had a heart attack, heart-related chest pains, heart disease, heart surgery, or been diagnosed with atrial fibrillation or any other abnormal heart rhythm?	☐	☐	
15. Have you ever had Sickle Cell Disease or Thalassemia?	☐	☐	
16. Have you ever had cancer? **If Yes, describe stage, treatment, and any recurrence.**	☐	☐	
17. Have you ever had a parasitic blood disease such as Chagas' disease or Babesiosis?	☐	☐	
18. Have you ever had a brain injury or head trauma, such as a concussion, skull fracture, or traumatic brain injury (also called TBI)? **If Yes, describe each injury, dates, symptoms, or any loss of consciousness.**	☐	☐	
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?	☐	☐	
20. Is there any other **past or present** health information that we have not discussed, and that you think we should be aware of?	☐	☐	
Question 21: Applies to donors of pediatric patients only	**YES**	**NO**	**Remarks**
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?	☐	☐	☐ NA
Section 2: Communicable Disease and Risk Assessment	**YES**	**NO**	**Remarks**
22. In the past 4 weeks have you had any vaccinations (other than smallpox) or any kind of shot?	☐	☐	
23. Are you planning to receive any vaccinations (including smallpox) or shots?	☐	☐	
24. In the past 8 weeks, have you received a smallpox vaccine? **If Yes, answer #24^{A}-#24^{C}. If No, go to #25.**	☐	☐	
24^{A}. When did you receive the vaccination?	**Date:**		
24^{B}. Did the scab fall off your skin by itself?	☐	☐	
24^{C}. 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?	☐	☐	
25. Have you had close contact with a 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 Yes, answer #25^{A}-#25^{C}. If No, go to #26.**	☐	☐	
25^{A}. When did the person receive the vaccination?	**Date:**		
25^{B}. When was the close contact?	**Date:**		
25^{C}. Have you had any new skin rash, sores, or an eye infection since the time of the contact?	☐	☐	
26. In the past 3 years, have you had malaria?	☐	☐	

Form M0345

DUKE UNIVERSITY HEALTH SYSTEM

History #:_____

	YES	NO	Remarks
27. In the past 3 years, have you **lived** (12 months or more) outside the United States or Canada?	☐	☐	
28. In the past 12 months, have you **traveled** (less than 12 months) outside the United States or Canada?	☐	☐	
29. In the past 120 days (4 months), have you been suspected of having or been diagnosed with West Nile Virus?	☐	☐	
29^{A}. When were you told this?	**Date:**		
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 Yes, answer #30^{A}-#30^{B}. If No, go to #31.**	☐	☐	
30^{A}: Have you ever had a dura mater (or brain covering) transplant for a head or brain injury?	☐	☐	
30^{B}: Have you ever received growth hormone made from human pituitary glands?	☐	☐	
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?	☐	☐	
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?	☐	☐	
33. In the past 12 months, have you had a tattoo? **If Yes, provide date applied, any signs of infection. Note if performed in a licensed establishment.**	☐	☐	
34. In the past 12 months, have you had an ear, skin, or body piercing using shared instruments or needles? **If Yes, provide date applied, any signs of infection. Note if performed in a licensed establishment.**	☐	☐	
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)?	☐	☐	
36. In the past 12 months, have you been held in jail, prison, juvenile detention, or lockup for more than 72 continuous hours?	☐	☐	
37. Have you traveled to Africa in the past 2 months?	☐	☐	
38. Have you been exposed to anyone with the Ebola Virus or anyone that has been exposed to the Ebola Virus?	☐	☐	
39. Since 1977, were you born in or have you lived in Africa **If Yes, answer #39^{A}- #39^{B}. If No, go to #40.**	☐	☐	
39^{A}: Was it Benin, Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, Nigeria Senegal, Togo, or Zambia?	☐	☐	
39^{B}: Did you receive a blood transfusion or medical treatment with a blood product while there?	☐	☐	

Form M0345

DUKE UNIVERSITY HEALTH SYSTEM

History #:_____

	YES	NO	Remarks
40. Since 1980, have you ever lived in or traveled to Europe? **(See reference B for a list of countries in Europe)** **If Yes, answer #40^{A}- #40^{D}. If No, go to 41.**	☐	☐	
40^{A}: 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 the Falkland Islands)	☐	☐	
40^{B}: Since 1980, did you receive a transfusion of blood or blood components while in the UK or France?	☐	☐	
40^{C}: Since 1980, have you spent time that adds up to 5 or more years in Europe, including time spent in the UK from 1980-1996?	☐	☐	
40^{D}: From 1980-1996, were you a member or dependent of a member of the U.S. military or a civilian-military employee? **If Yes, answer #40^{D1} and #40^{D2}. If No, got to #41.**	☐	☐	
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 the Netherlands?	☐	☐	
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?	☐	☐	
41. Have you had or anyone in your household had a medical diagnosis of ZIKA virus infection in the past 6 months?	☐	☐	
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? **Staff will refer to CDC.GOV for Zika risk areas.**	☐	☐	
Section 3. Sexual Contact	**YES**	**NO**	**Remarks**
43. Are you sexually active? **If you are not sexually active, mark "NO"; go to question #63. If you are sexually active, see Attached Reference C "Important Information" Pamphlet.**	☐	☐	
The section applies to female donors only (#44 -#48):	**YES**	**NO**	☐ **Male donor; Go to Question #49**
44. How many times have you been pregnant? **If "0" mark N/A, go to #47**	#		☐ **N/A**
45. In the past 6 weeks, have you been pregnant or are you now pregnant?	☐	☐	
46. Have you had any health problems associated with or caused by pregnancy?	☐	☐	
47. Do you plan to or is there any chance that you will become pregnant within the next 6 months?	☐	☐	
48. 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?	☐	☐	

Form M0345

DUKE UNIVERSITY HEALTH SYSTEM

History #:_____

	YES	NO	Remarks
The section applies to male donors only (#49):	**YES**	**NO**	☐ **Female donor; Go to Question #50**
49. In the past 5 years, have you had sex, even once, with another male?	☐	☐	
This section applies to all sexually active donors (#50-#62):	**YES**	**NO**	**Remarks**
50. In the past 5 years, have you exchanged money, drugs, or other payment in exchange for sex?	☐	☐	
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?	☐	☐	
52. Have you had sex with a person who has resided in or traveled to, an area with active ZIKA virus transmission within the past 6 months?	☐	☐	
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?	☐	☐	
54. Have you ever tested positive for syphilis, including screening tests, or ever been treated for syphilis within the last 12 months?	☐	☐	
55. Have you ever tested positive for HIV or do you have AIDS, including screening tests?	☐	☐	
56. Do you have 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	☐	☐	
57. Have you ever tested positive for HTLV (Human T-lymphotropic virus), including screening tests?	☐	☐	
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)?	☐	☐	
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?	☐	☐	
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?	☐	☐	

Form
M0345

DUKE UNIVERSITY HEALTH SYSTEM

History #:_____

	YES	NO	Remarks
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?	☐	☐	
62. In the past 12 months, have you had sex, even once, with anyone who has AIDS or tested positive for the AIDS virus?	☐	☐	
Section 4. Questions	**YES**	**NO**	**Remarks**
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.**	☐	☐	

Form
M0345

DONOR - PLEASE READ CAREFULLY

Donor Verification and Authorization History #: _____

- I have had the opportunity to ask questions about the information requested in this questionnaire.
- I understand that the requested information is important because if I am at risk for infection due to AIDS or other communicable disease agents or diseases, my donated cells may transmit these diseases to the patient receiving these cells.
- I have truthfully answered all of the questions on this questionnaire.
- I authorize the release of the information on this questionnaire to the transplant center and the CIBMTR.
- I understand the recipient of my donated cells may be advised of any communicable disease risks.
- I understand that authorizing this release of information is voluntary and that I can refuse to sign this document.

_____ _____ _____
Signature of Patient, Parent (if a minor) or Legally Authorized Representative (LAR) Date Time

_____
Relationship to Patient (If Other Than Patient)

Donor Center Staff Review

This form was completed by the following method:

☐ This form was self-administered by the donor and reviewed for completeness.
☐ I performed an oral interview with the donor (including reading Reference A, Reference B, and Reference C, if applicable, and Donor Verification and Authorization) and completed this form.

☐ An interpreter was required: _____
☐ N/A Interpreter Name

☐ Arm inspection was performed by: _____
☐ N/A

I have reviewed this form and verbally verified answers with the donor. I addressed any questions the donor had and clarified health information as needed.

_____
Donor Center Staff's Name (please print)

_____ _____/_____/_____
Donor Center Staff's Signature Date

Medical Director/Designee Review and Approval:

_____
Medical Director's/Designee's Name (please print)

_____ _____/_____/_____
Medical Director's/Designee's Signature Date

Reference A				
Medication Brand Name:	**Generic Name**	**Given for:**	**Deferred Time:**	**Why these medications affect your donation:**
Proscar*∞	Finasteride*	Prostate gland enlargement and baldness	1 month	These medications can cause birth defects and/or death of an unborn baby. Your donated blood could contain high enough levels to damage the unborn baby if transfused to a pregnant woman. Once the medication has cleared from your blood, you may donate again. Following the last dose, the deferral period is:
Avodart* Jalyn*	Dutasteride*	Prostate gland enlargement and BPH	6 months	
Propecia*	Finasteride*	Baldness	1 month	
Thalomid*	Thalidomide*	Multiple Myeloma	1 month	
Accutane*∞ Absorica* Amnesteem* Claravis* Sotret* Myorisan* Zenatane*	Isotretinoin*	Severe Acne	1 month	
Cellcept*	Mycophenolate mofetil*	Immunosuppressant	6 months	
Erivedge* Odomzo*	Vismodegib* Sonidegib*	Basal Cell Skin Cancer	24 months	
Aubagio*	Teriflunomide*	Relapsed Multiple Sclerosis	24 months	
Arava*	Leflunomide*	Rheumatoid Arthritis	24 months	
Soriatane*	Acitretin	Severe psoriasis	36 months	
Tegison*∞	Etretinate	Severe psoriasis	Indefinite	
Growth Hormone from Human Pituitary Glands*∞		Delayed/impaired growth (used only until 1985)	Indefinite	This was prescribed until 1985 for children with delayed or impaired growth. The hormone was obtained from human pituitary glands, which are found in the brain. Some people who took this hormone developed a rare nervous system condition called Creutzfeldt-Jakob Disease (CJD, for short).
Insulin from Cows (Bovine or Beef Insulin)*		Diabetes	Indefinite	This is an injected material used to treat diabetes. If this insulin was imported into the US from countries in which "Mad Cow Disease" has been found, it could contain material from infected cattle. There is concern that "Mad Cow Disease" may be transmitted by transfusion.
Hepatitis B Limmune Globulin*	HBIG*	Hepatitis B Exposure	12 months	This is an injected material used to prevent infection **following exposure** to Hepatitis B. HBIG does not prevent Hepatitis B infection in every case, therefore, persons who have received HBIG must wait to donate.
Experimental Medications or Unlicensed Vaccines*		Usually a research protocol.	12 months	Unlicensed vaccines are usually associated with a research protocol and the effect on blood transmission is unknown.

Key: **FDA** Medication Deferral List (∞) and **AABB** Medication Deferral List (*)

Update 3/20/2020

Reference B:		
Country	**Country**	**Country**
Albania	Hungary	Slovenia
Austria	Ireland (Republic of)	Spain
Belgium	Italy	Sweden
Bosnia-Herzegovina	Liechtenstein	Switzerland
Bulgaria	Luxembourg	United Kingdom: England, Northern Ireland Scotland, Wales, Isle of Man, Channel Islands, Gibraltar, Falkland Islands
Croatia	Macedonia	
Czech Republic	Netherlands (Holland)	
Denmark	Norway	
Finland	Poland	
France	Portugal	
Germany	Romania	Yugoslavia (the Federal Republic of) Kosovo, Montenegro, Serbia
Greece	Slovak Republic	
*Also see *Medical History Exclusion Criteria* for additional guidance on exclusion risk factors.		

Form
M0345

Reference C	Sexual Contact: See Question # 43

Important Information You Must Know About Stem Cell or Other Cellular Therapy Donations

This information sheet explains how YOU can help make the donation process safe for yourself and the patient who is scheduled to receive your stem cells or other cellular therapy donations.

Please read this information **BEFORE** you donate. If you have questions, please ask your medical team.

You will be asked to complete a health history questionnaire. The questionnaire asks questions that help you provide a good health history so the medical team can make the best plan for you and the patient receiving your stem cells or other cellular therapy donations.

Why we ask questions about sexual contact:

Sexual contact may cause contagious diseases such as but not limited to HIV, hepatitis, or the Zika virus to get into the bloodstream and be spread through transfusions.

Definition of "sexual contact": The words "have sexual contact with" and "sex" are used in some of the questions and applies to any of the activities below, whether or not a condom or other protection was used:

1. Vaginal sex (contact between penis and vagina);
2. Oral sex (mouth or tongue on someone's vagina, penis, or anus);
3. Anal sex (contact between penis and anus).

Why we ask questions about travel to or birth in other countries:

Blood donor tests may not be available for some contagious diseases that are found only in certain countries. If you were born in, have lived in, or visited certain countries, you may not be eligible to donate to another person. However, if you are donating to yourself, you will be eligible.

What happens when you donate?

Your blood may be tested for evidence of viruses and other germs that can be transmitted from one person to another through the blood. These include but are not limited to Hepatitis B and C, HIV, HTLV, CMV, Syphilis. Toxoplasmosis, HSV, VZV, and Epstein Barr Virus (EBV).

If your tests are positive and you are donating to yourself, your physician/designee may talk with you about those results.

If your tests are positive and you are donating to another person, the physician/designee will discuss your results and the risks of using your cells as a donation for the patient. In many cases, it will be safe to use your cells even if some of these tests are positive. However, in the majority of circumstances, if the tests for HIV, HTLV, Hepatitis B, or Hepatitis C from your blood are positive, your cells will ***not*** be used.

When required, we report donor information, including test results, to local and/or state health departments, military medical commands, and regulatory agencies.

Signature Manifest

Document Number: APBMT-COMM-001 FRM3 **Revision:** 02
Title: Donor Health History Questionnaire FRM3
Effective Date: 01 Mar 2021

All dates and times are in Eastern Time.

APBMT-COMM-001 FRM3 Donor Health History Questionnaire

Author

Name/Signature	Title	Date	Meaning/Reason
Mary Beth Christen (MC363)		27 Oct 2020, 02:13:38 PM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
Nelson Chao (CHAO0002)		28 Oct 2020, 08:31:11 AM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		28 Oct 2020, 09:05:01 AM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Bing Shen (BS76)		28 Dec 2020, 06:33:46 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Betsy Jordan (BJ42)		04 Feb 2021, 12:05:44 PM	Approved