



Name: \_\_\_\_\_ Date: \_\_\_\_\_  
 (Please print)

Donation Cycle # \_\_\_\_\_

**Risk Factor Questionnaire**

FDA regulations require that an eligibility determination be performed for egg and sperm donors, based on testing and screening for relevant communicable diseases. This is for the protection of possible recipients of the tissue, and well as those people who may handle or come in contact with tissue. Please read and answer the following questions truthfully and to the best of your knowledge. We recognize that some of the questions are of a sensitive nature, and thank you for providing the most accurate information. **Please describe any "yes" answers on the bottom of this form.**

Group 1		For Office Use Only
1. Have you or a family member had Creutzfeldt-Jakob ("Mad Cow") disease or Variant Creutzfeldt-Jakob disease or risk for it?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
2. Were you a member of the US military, a civilian military employee, or a dependent of a member of the US military who spent a total of 6 months on or associated with a military base stationed in Belgium, Netherlands, or Germany between 1980-1990, and/or Spain, Portugal, Turkey, Italy or Greece between 1980-1996?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
3. Have you visited or lived in the United Kingdom (UK) for three months or more cumulatively between 1980-1996? (UK includes: England, Scotland, Wales, Northern Ireland, Isle of Man, Channel Islands, Gibraltar, Falkland Islands)	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
4. Have you had a blood transfusion in the United Kingdom (UK) or France between 1980 to present?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
5. Have you traveled or lived a cumulative time of 5 years or more since 1980 to present in any combination of countries in Europe?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
6. Have you received Human Pituitary Growth Hormone (used until 1985) or dura matter (brain covering) graft?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
7. Have you injected Bovine (beef) insulin (used to treat diabetes) since 1980?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
8. Do you have a <u>biologic relative</u> who has been diagnosed with CJD? Biologic relative in this setting means mother, father, sibling, grandparent, aunt, uncle or children.	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
9. Have you been diagnosed with dementia or any degenerative or demyelinating disease of the central nervous system?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
Group 2		
10. Have you ever had prior reactive (positive) screening for HIV?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
11. Have you had sex with someone who has been diagnosed with HIV?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
12. Have you used needles to take injectable drugs for non-medical use, including steroids, or anything not prescribed by a doctor (including intravenous, intramuscular, and subcutaneous injections) within the past five (5) years?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
13. Have you engaged in sex in exchange for money or drugs in previous 5 years?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
14. Have you received human-derived clotting factor concentrates for a bleeding disorder such as hemophilia or related blood clotting disorder within the past 5 years?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
15. Have you ever had sexual contact or participated in sexual activity with someone of the same sex (male-to-male contact) in previous 5 years?	<input type="checkbox"/> No <input type="checkbox"/> Yes N/A	<input type="checkbox"/> Refer to SOP

16. Have you had sexual contact in the past 12 months with anyone described in questions 12-15?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
17. Have you or your sexual partner were born or lived in certain countries in Africa after 1977? (Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, or Nigeria).	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
18. Have you received a blood transfusion or any medical treatment that involved blood in the countries <i>listed question # 17 above</i> , after 1977?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
<b>Group 3</b>		
19. Do you have unexplained weight loss (10 pounds or more in less than 2 months), night sweats, or swollen lymph nodes (lumps in your neck, armpits, or groin) for longer than one month?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
20. Have you had an unexplained temperature of >100.5 F for 10 or more days?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
21. Have you had unexplained white spots or unusual blemishes in mouth?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
22. Do you have blue/purple spots under skin or mucous membranes?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
23. Do you have unexplained cough, shortness or breath, persistent diarrhea or other infection?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
<b>Group 4</b>		
24. Have you ever had prior reactive (positive) screening test for HTLV?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
25. Have you ever tested positive for Adult T-Cell Leukemia?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
26. Have you ever experienced weakness in your lower extremities (Paraparesis)?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
<b>Group 5</b>		
27. Have you ever had prior reactive (positive) screening for hepatitis B or C virus?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
28. Have you had unexplained jaundice (yellow skin) or enlarged liver?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
29. Have you been diagnosed with clinical, symptomatic viral Hepatitis after age 11?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
If yes, at the time of illness, was it documented as Hepatitis A?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> N/A	<input type="checkbox"/> Refer to SOP
30. Have you received a tattoo or body piercing within the past 12 months in which shared instruments are known to have been used?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
31. Have you received a blood transfusion in the last 12 months (excluding your own "autologous" blood)?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
32. Have you been exposed in the preceding 12 months to known or suspected HIV, HBV or HCV-infected blood through needle stick or through contact with an open wound, non-intact skin or mucous membrane?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
33. Have you had close contact within 12 months with another person having clinically active hepatitis B or hepatitis C infection (i.e. living in the same household, where sharing of kitchen and bathroom facilities occurs regularly)?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
34. Have you ever been incarcerated (jailed) for more than 72 hours during the past 12 months?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
<b>Group 6 Within past 12 months:</b>		
35. Have you had sex with any person known or suspected to have clinically active Hepatitis B infections, or Hepatitis C infection?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
<b>Group 7 (Only to be used when person-to-person transmission of SARS-CoV occurring in the world (Check CDC site) If Omit box checked, check N/A</b>		
36. Do you currently have/or within past 7 days, had a moderate respiratory illness, fever,	<input type="checkbox"/> Omit <input type="checkbox"/> No	<input type="checkbox"/> Complete <input type="checkbox"/> Refer to SOP

cough, and shortness of breath or difficulty breathing?	<input type="checkbox"/> Yes <input type="checkbox"/> N/A	
37. Do you have a recent X-ray showing evidence of pneumonia within past 12 months?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> N/A	<input type="checkbox"/> Refer to SOP
38. Have you recently been diagnosed with Respiratory Distress Syndrome?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> NA	<input type="checkbox"/> Refer to SOP
39. Have you had recent contact (within 14 days) with any person suspected with SARS?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> N/A	<input type="checkbox"/> Refer to SOP
40. Have you recently traveled to or resided in an area (within 14 days) affected by SARS?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> N/A	<input type="checkbox"/> Refer to SOP
41. In the past 28 days have you been exposed to, treated for or do you have SARS?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> N/A	<input type="checkbox"/> Refer to SOP
<b>Group 8</b>		
42. Have you had an unexplained fever, fast heart rate and fast respiratory rate within past 7 days?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
43. Have you been diagnosed with or treated for Sepsis or have elevated white blood cell count or positive blood cultures associated with the condition described above within the last 7 days?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
44. Do you currently have severe signs and symptoms of Sepsis; unexplained low oxygen in the blood, very low urine output, altered mental functioning, low blood pressure?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
<b>Group 9</b>		
45. Have you been treated for Syphilis in the past 12 months?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
46. Have you been treated for Gonorrhea or Chlamydia in the past 12 months?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
47. Have you contracted Gonorrhea, Chlamydia, venereal warts (HPV), or genital herpes in the past 12 months?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
<b>Group 10</b>		
48. Have you had a Smallpox vaccination in the past 21 days? Or in the preceding 8weeks?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
If yes, did the scab separate spontaneously	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> N/A	<input type="checkbox"/> Refer to SOP
49. If yes, did you develop any complications (i.e. skin rashes/sores beyond the vaccination site infection of the cornea, or general illness related to the vaccination)?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> N/A	<input type="checkbox"/> Refer to SOP
50. Have you developed skin rashes/sores since close contact with someone who received a Small Pox vaccination?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
<b>Group 11</b>		
51. Have you had a medical diagnosis of WNV (including diagnosis based on symptoms and laboratory results, or confirmed WNV viremia)?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
<b>Within the past 7 days:</b>		
52. Have you had fever and headache, body aches or eye pain?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
53. Have you had a skin rash on the trunk of your body?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
54. Have you had a severe illness: encephalitis, meningitis, paralysis?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
55. Have you had severe illness with headache, high fever, neck stiffness, disorientation, coma or tremors?	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
56. Have you experienced convulsions, muscle weakness or paralysis?	<input type="checkbox"/> No	<input type="checkbox"/> Refer to SOP

Yes

Group 12		
57. Are you a recipient or have you had intimate contact of a xenotransplantation product recipient? (surgical transfer of cells, tissues, or especially whole organs from one species to another)	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> Refer to SOP
58. If yes to question #57 or if this person is in your household, have you been exposed to blood, saliva, or other body fluids from this person?	<input type="checkbox"/> No <input type="checkbox"/> Yes N/A	<input type="checkbox"/> Refer to SOP

Please describe any “YES” answers below:

---



---



---



---

By signing this form I represent and warrant that I have read the above questions and have answered them truthfully and to the best of my knowledge. If I was uncertain about a question, I was given the opportunity to ask the physician and/or nurse for clarification and then answered the question truthfully and to the best of my knowledge. I understand that I am being asked **not** to participate in any of the above high-risk activities described in the questions contained in this questionnaire (including but not limited to tattooing, body piercing, multiple partners, unprotected sex, recreational drug use, etc.) during the donation cycle (IVF) and will inform the nursing staff if I do. I agree to practice safe sex during this time period to prevent communicable disease exposure and prevent any unwanted pregnancy. I understand that if I do participate in any of the above high-risk activities that I report this to the physicians or nursing staff at SRM and that I may be asked to postpone the donation or possibly be excluded from the donor program, IVF gestational carrier cycle or may disqualify Cryopreserved embryos from being donated in the future. By participating in any high-risk activities such as those described herein, I understand that legal recourse by the recipient couple or individual receiving the donation is possible should my actions cause any adverse affect. I agree to indemnify, defend and hold harmless SRM, its doctors and employees from any and all claims, losses, liabilities and demands suffered by any of them as a result of my participation in any high-risk activities or behavior and/or any untruthfulness or inaccuracy by me concerning the same.

**Initial Screening:**

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Interviewer: \_\_\_\_\_ Date: \_\_\_\_\_

FCI Physician: \_\_\_\_\_ Date: \_\_\_\_\_

**Risk Factor Questionnaire Status:**

A) Approved for tissue donation: \_\_\_\_\_

B) Rejected for tissue donation: \_\_\_\_\_

FCI to specify time frame and medical reason for deferral, per SOP: \_\_\_\_\_

---