

**California Fertility Partners/Reproductive Technology Laboratories**

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**Screening of potential donors of oocytes or sperm**

In order to safeguard those who donate and receive tissue, the FDA requires screening and testing of the potential donors. The questionnaire below seeks your complete honesty and accuracy. If you have any questions during the screening process, please ask your nurse or physician for assistance.

<b>Review of risks for Creutzfeldt-Jakob disease</b>		Yes	No	C	F	P
				comments		
1	Have you or a family member have confirmed (gene sequencing) Creutzfeldt-Jakob (“Mad Cow”) disease, Variant Creutzfeldt-Jakob disease, or risk for CJD? <ul style="list-style-type: none"> <li>If family members have confirmed diagnoses of CJD or vCJD, how many family members were diagnosed? [            ]</li> </ul>					
	Did you reside in the UK (includes England, Northern Ireland, Scotland, Wales, Isle of Man, Channel islands) for ≥3 months between 1980 and 1996?					
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 northern Europe (Germany, Belgium, Netherlands) between 1980 -1990?					
	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 Spain, Portugal, Turkey, Italy or Greece between 1980 and 1996?					
3	Have you visited or lived in the UK for three or more months between 1980 and 1996?					
4	Have you received blood or blood components in the UK or France since 1980?					
5	Have you traveled or lived a cumulative time of 5 years or more since 1980 to the present in any combination of countries in Europe?					
6	Have you received human pituitary-derived growth hormone (used until 1985) or a non-synthetic dura mater (brain covering) graft?					
7	Have you been treated with bovine (beef) insulin (used to treat diabetes) since 1980?					
8	Do you have a biologic relative who has been diagnosed with CJD? (Biologic relative in this setting means father, sibling, grandparent, aunt, uncle or children).					
9	Have you been diagnosed with dementia or any degenerative or demyelinating disease of the central nervous system?					
	Have you been diagnosed with any other neurological disease of unknown cause?					
	Have you, or your sexual partner, resided in Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger or Nigeria after 1977?					
<b>Review of risks for HIV</b>		Yes	No	C	F	P
				comments		
10	Have you ever had prior reactive (positive) screening test for HIV?					

11	Have you had sex with some-one who has been diagnosed with HIV?				
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 5 years?				
13	Have you engaged in sex in exchange for money or drugs in the past 5 years?				
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?				
15	Have you participated in male-to-male sexual activity, or participated in sexual activity with a man who had male-to-male sexual activity, in the past 5 years?				
16	Were you or your sexual partners born or lived in certain countries in Africa after 1977				
17	Have you received a blood transfusion or any medical treatment that involved blood in Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger or Nigeria after 1977?				
18	Have you had sexual contact in the past 12 months with anyone described in questions 12-17?				
<b>HIV signs and symptoms</b>		Yes	No	C	F P comments
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?				
20	Have you had an unexplained temperature of >100.5°F for 10 or more days?				
21	Have you had unexplained white spots or unusual blemishes in the mouth?				
22	Do you have blue/purple spots under the skin or mucous membranes?				
23	Do you have unexplained cough, shortness of breath, persistent diarrhea or other infection(s)?				
<b>Risk of HTLV (Human T-lymphotrophic virus)</b>		Yes	No	C	F P comments
24	Have you ever had a prior reactive (positive) screening test for HTLV?				
25	Have you ever tested positive for Adult T-cell leukemia.				
26	Have you ever experienced weakness in your lower extremities (paraparesis)?				
<b>Risk of Hepatitis infection</b>		Yes	No	C	F P comments
27	Have you ever had prior reactive (positive) screening for Hepatitis B or C virus?				
28	Have you had unexplained jaundice (yellow skin, yellowing of the whites of the eyes) or enlarged liver?				
29	Have you been diagnosed with clinical, symptomatic viral hepatitis since age 11? • If 'Yes', at the time of illness, was it documented as being caused by hepatitis A, Epstein-Barr Virus (EBV) or cytomegalovirus (CMV)?				
30	Have you received a tattoo or body piercing within the past 12 months in which sterile procedures were not used?				
31	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?				
32	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?				
33	Have you ever been incarcerated (jail, juvenile detention, lock-up or prison) for more than 72 hours during the past 12 months?				

<b>Risk factor assessment</b>		Yes	No	C	F	P
				comments		
34	Have you had sex with any person known or suspected to have clinically active hepatitis B infections or hepatitis C infection?					
<b>Risk of sepsis</b>		Yes	No	C	F	P
				comments		
41	Have you had an unexplained fever (>100.4°F), fast heart rate (>90 beats/minute) and fast respiratory rate (>20 breaths/minute) within the past 7 days?					
42	Have you been diagnosed with or treated for sepsis or have elevated white blood cell count (>12,000/mm <sup>3</sup> ) or positive blood cultures associated with sepsis within the past 7 days?					
43	Do you currently have severe signs and symptoms of sepsis; unexplained low oxygen in the blood, very low urine output, altered mental functioning or low blood pressure?					
<b>Risk of Syphilis/STD infection</b>		Yes	No	C	F	P
				comments		
44	Have you been treated for Syphilis in the past 12 months?					
45	Have you been treated for Gonorrhea in the past 12 months?					
46	Have you contracted Chlamydia, venereal warts (HPV) or genital herpes in the past 12 months?					
<b>Risk of Vaccinia (Smallpox)</b>		Yes	No	C	F	P
				comments		
47	Have you had a Smallpox vaccination in the past 8 weeks? <ul style="list-style-type: none"> <li>• If 'Yes', did the scab separate spontaneously?</li> <li>• 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?</li> </ul>					
48	Have you developed skin rashes/sores/skin lesions since close contact with someone who received a Small pox vaccination? <ul style="list-style-type: none"> <li>• If 'Yes', did the scab(s) separate spontaneously?</li> </ul>					
<b>Risks of West Nile virus</b>		Yes	No	C	F	P
				comments		
50	Have you had a medical diagnosis of WNV (including diagnosis based on symptoms and laboratory results or confirmed viremia)? <ul style="list-style-type: none"> <li>• If 'Yes', was the diagnosis supported by an FDA licensed or investigational WNV NAT?</li> </ul>					
51	Within the past 7 days, have you; <ul style="list-style-type: none"> <li>• Had a fever and headache, body aches or eye pain?</li> <li>• Had swollen lymph glands?</li> <li>• Had a skin rash on the trunk of the body?</li> <li>• Had a severe illness; encephalitis, meningitis, meningoencephalitis, paralysis?</li> <li>• Had severe illness with headache, high fever, neck stiffness, disorientation, coma or tremors?</li> <li>• Experienced convulsions, muscle weakness or paralysis?</li> </ul>					
<b>Xeno-transplantation</b> (transplant or other medical procedure that involved being exposed to live cells, tissues or organs from an animal)		Yes	No	C	F	P
				comments		
57	Are you a recipient, or have you had intimate contact with a recipient, of a xeno-transplantation product? (Surgical transfer of live cells, tissues or whole organs from an animal). <ul style="list-style-type: none"> <li>• If 'yes', or if this person resides in your household, have you been exposed to blood, saliva, or other body fluids from this person?</li> </ul>					


I certify that all the information provided above is complete and true to the best of my knowledge.

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 Donor name (Print) Donor signature Date

\_\_\_\_\_ /\_\_\_\_\_/\_\_\_\_\_  
 Date CFP witness name (Print) Donor signature

RCDADs questionnaire