Directed Semen Donor Eligibility Requirements

Directed (known) reproductive donors using the University Andrology Sperm Banking Program must follow FDA requirements to prevent the transmission of relevant communicable disease agents.

The UIC Andrology Lab is responsible for the processing, storage and distribution of semen from directed donors. Testing and screening are the responsibility of the donor/recipient.

The donor/recipient must consult with a physician to determine donor eligibility by reviewing the donor’s relevant medical records for risk factors for, and clinical evidence of, relevant communicable disease agents and diseases.

Testing must be done using ViroMed Laboratories (Donor Screening Panel # 139496). LabCorp testing centers offer this service.

**TESTING MUST BE COMPLETED WITHIN 7 DAYS OF EACH SEMEN COLLECTION**

1) HIV, type 1 and HIV-1 NAT (nucleic acid amplification test method)
2) HIV, type 2
3) Hepatitis B surface antigen (HBsAg) and Hepatitis B core antigen (anti-HBc)
4) Hepatitis C (anti-HCV) and HCV NAT (nucleic acid amplification test)
5) HTLV types I and II
6) Treponema pallidum (syphilis) [FDA-licensed, approved or cleared test].
7) CMV (cytomegalovirus) total IgG and IgM. ** See note at bottom of page.
8) Chlamydia trachomatis
9) Neisseria gonorrhoea
10) West Nile Virus NAT

Copies of test results must be submitted to the requesting physician as well as the Andrology lab. Donor eligibility form will be completed and sent to physician. The physician will be notified of any reactive (positive) results. It will be up to the discretion of the physician whether or not to use the specimen.

Semen specimens will be held in the quarantine tank until all testing is completed. Specimens with a reactive test result will be released with the following notification: “Warning: Advise patient of communicable disease risks” and “Warning: Reactive test results for (name of the disease).” Biohazard label included.

** For positive CMV results, include sheet explaining CMV Antibody Testing.

Version: 3/1/2021
Zika Virus Screening for Directed Semen Donors

FDA guidance recommends physician review of relevant medical records for directed semen donors including a review of travel history. The review must indicate that a potential donor is free from risk factors or clinical evidence of Zika virus infection for the purpose of determining donor eligibility.

The directed donor will be considered **ineligible** if the following apply:

1. He has a medical diagnosis of Zika infection in the past 6 months.
2. Residence in, or travel to, an area with active Zika virus transmission within the past 6 months.
3. Sex within the past 6 months with a male who is known to have either of the risk factors listed above.

The directed semen donor’s physician must complete and sign the screening questionnaire below.

<table>
<thead>
<tr>
<th>Zika Virus Screening Questionnaire</th>
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</thead>
<tbody>
<tr>
<td><strong>Physician’s Name</strong></td>
</tr>
<tr>
<td><strong>Directed Semen Donor’s Name</strong></td>
</tr>
</tbody>
</table>

1. Has the above named Directed Semen Donor had a medical diagnosis of Zika infection in the past six months?  
   - Circle Yes or No
     - Yes
     - No

2. Has the above named Directed Semen Donor resided in or traveled to an area with active Zika virus transmission within the past 6 months?  
   - Circle Yes or No
     - Yes
     - No

3. Has the above named Directed Semen Donor had sex within the past 6 months with a male who is known to have either of the risk factors listed above?  
   - Circle Yes or No
     - Yes
     - No

I, the undersigned physician certify that I have screened the above named Directed Semen Donor for the Zika virus risk factors and have determined that he is eligible.

- Circle Yes or No
  - Yes
  - No

**Physician’s Signature**

**Date**
DIRECTED DONOR MEDICAL HISTORY INTERVIEW FORM

Directed Donor Name: __________________________________________________________ Date: ______________________

Photo Identification: _____________________________ ID Checked by: ______________________________

Cells / Tissues Donated: ___________ Sperm ___________ Date of Last Interview: ______________________

Recovery Method: Masturbation
Donation Type: Directed Donor

___ yes ___ no 1. (Men only) Have you had sex with another man in the preceding five years?

___ yes ___ no 2. Have you injected drugs for a non-medical reason in the preceding five years, including intravenous, intramuscular, or subcutaneous injections?

___ yes ___ no 3. Do you have hemophilia or another related clotting disorder? If yes, have you received human-derived clotting factor concentrates in the preceding five years?

___ yes ___ no 4. Have you engaged in sex in exchange for money or drugs in the preceding five years?

___ yes ___ no 5. Have you engaged in sex in exchange for money or drugs in the preceding five years?

___ yes ___ no 6. Have you been exposed in the preceding 12 months to known or suspected HIV, HBV, and /or HCV – infected blood through percutaneous inoculation (e.g., needle-stick) or through contact with an open wound, non-intact skin, or mucous membrane?

___ yes ___ no 7. Have you been incarcerated for more than 72 consecutive hours during the previous 12 months?

___ yes ___ no 8. Have you lived with (resided in the same dwelling) another person who has hepatitis B or clinically active (symptomatic) hepatitis C infection in the preceding 12 months?

___ yes ___ no 9. Have you had a tattoo, ear piercing, or body piercing in the last 12 months in which sterile procedures were not used, e.g., contaminated instruments and/or ink were used, or shared instruments that had not been sterilized between uses were used?

___ yes ___ no 10. Have you been diagnosed with clinical, symptomatic viral hepatitis after your 11th birthday? Unless evidence from the time of illness documents that the hepatitis was identified as being caused by hepatitis A virus(e.g., a reactive IgM anti-HAV test), Epstein-Barr Virus (EBV), or cytomegalovirus (CMV)?

___ yes ___ no 11. Have you had a recent smallpox vaccination (vaccinia virus) in the last 60 days? **Donors with no vaccinia complications should be deferred until the vaccination scab has separated spontaneously, or for 21 days post-vaccination, whichever is the later date, and until the physical examination or physical assessment includes confirmation that there is no scab at the vaccination site. In cases where the scab was removed before separating spontaneously, the donor should be deferred for two months after vaccination. For persons who experienced vaccinia complications, the donor should be deferred until 14 days after all vaccinia complications have been completely resolved.**
___yes___no 12. Do you have a clinically recognizable vaccinia virus infection contracted by close contact with someone who received the smallpox vaccine? If the answer is yes to this question, how and when was the scab lost? The donor’s skin should be examined. **Defer donation from living donors until the scab has spontaneously separated. If the scab was otherwise removed, defer donor for 3 months from the date of vaccination of the vaccine recipient. Defer persons who develop other complications of vaccinia infection acquired through contact with a vaccine recipient until 14 days after all vaccinia complications have completely resolved.**

___yes___no 13. Have you had a medical diagnosis or suspicion of WNV infection (based on symptoms and/or laboratory results, or confirmed West Nile Virus NV viremia)? **If the answer is yes to this question defer donation for 120 days from diagnosis or onset of symptoms, whichever is the later date or 28 days after condition has resolved.**

___yes___no 14. Have you tested positive or reactive for WNV infection using and FDA-licensed or investigational WNV NAT donor screening test in the preceding 120 days? **If the answer is yes to this question defer donation for 120 days from diagnosis or onset of symptoms, whichever is the later date or 28 days after condition has resolved.**

___yes___no 15. Have you had both a fever and a headache (simultaneously) during the 7 days prior to donation? **If yes, defer donation for 120 days from the onset of illness.**

___yes___no 16. Have you been diagnosed with Zika virus infection, been in an area with active Zika virus transmission, or had sex with a male with either of those risk factors, within the past six months?

___yes___no 17. Have you been treated for syphilis within the preceding 12 months? **If yes, defer donation until evidence is presented that the treatment occurred more than 12 months ago and was successful.**

___yes___no 18. Have you been diagnosed with or treated for Chlamydia in the preceding 12 months? **If yes, defer donation until evidence is presented that the treatment occurred more than 12 months ago and was successful.**

___yes___no 19. Have you been diagnosed with or treated for Gonorrhea in the preceding 12 months? **If yes, defer donation until evidence is presented that the treatment occurred more than 12 months ago and was successful.**

___yes___no 20. Have you ever been diagnosis with vCJD or any other form of CJD?

___yes___no 21. Have you ever had a diagnosis of dementia or any degenerative or demyelinating disease of the central nervous system (CNS) or other neurological disease of unknown etiology?

___yes___no 22. Have you ever received a non-synthetic dura mater transplant?

___yes___no 23. Have you ever received human pituitary-derived growth hormone?

___yes___no 24. Have you ever had a blood relative diagnosed with CJD?

___yes___no 25. Have you spent three months or more cumulatively in the United Kingdom (U.K.) from the beginning of 1980 through the end of 1996?

___yes___no 26. Are you a current or former U.S. military member, civilian military employee, or dependent of a military member or civilian employee who resided at U.S. military bases in Northern Europe (Germany, Belgium and the Netherlands) for 6 months or more cumulatively from 1980 through 1990, or elsewhere in Europe (Greece, Turkey, Spain, Portugal, and Italy) for 6 months or more cumulatively from 1980 through 1996?
Directed Donor Name ______________________________________________

___yes ___no 27. Have you lived 5 years or more cumulatively in Europe from 1980 until the present (note this criterion includes time spent in the U.K. from 1980 through 1996)?

___yes ___no 28. Have you received any transfusion of blood or blood components in the U.K. or France between 1980 and the present?

___yes ___no 29. Have you injected bovine insulin since 1980? Can you confirm that the product was not manufactured after 1980 from cattle in the U.K.?

___yes ___no 30. Are you or any of your close contacts (persons with whom you have engaged in activities that could result in intimate exchange of body fluids, including blood or saliva) a xenotransplantation product recipient? Have you, your sexual partner, or any member of his/her household ever had a transplant or other medical procedure that involved being exposed to live cells, tissues, or organs from a nonhuman animal source, or human body fluids, cells, tissues, or organs that have had ex vivo contact with live nonhuman animal cells, tissues, or organs?

___yes ___no 31. Have you had a transfusion or received blood or blood products in the last 48hrs?

The following questions need only be asked if there is a SARS outbreak in the world. Contact the CDC website (http://www.cdc.gov) or call CDC (888-246-2675) to obtain the up-to-date information concerning areas affected by SARS. **If there is cases of SARS ask the following questions, otherwise note N/A.**

___yes ___no 32. Have you traveled to or resided (the areas affected) in the last 14 days?

___yes ___no 33. Have you had close contact with someone who has traveled to or resided (the areas affected) in the last 14 days?

___yes ___no 34. Have you been treated for SARS or suspected you had SARS in the last 28 days?

___yes ___no 35. Have you had close contact within the previous 14 days with persons with SARS or suspected SARS.

---------------------------------------------------------------------

Authorized person completing initial Medical History Interview form:

_____________________________________________________________
Print

________________________________________  _________________
Signature                                      Date
**DIRECTED DONOR PHYSICAL ASSESSMENT FORM**

Directed Donor Name: ___________________________________________ Date: ______________________

Photo Identification ___________________________ ID Checked by __________________________________

Cells / Tissues Donated: Sperm ___________________________ Date of Assessment ______________________

Recovery Method: Masturbation

Donation Type: Directed Donor

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**PHYSICAL ASSESSMENT**

*(is there evidence of the following - attach additional page for comments if needed)*

<table>
<thead>
<tr>
<th>Condition</th>
<th>Yes</th>
<th>No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor Basic Hygiene</td>
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<tr>
<td>Genital lesions</td>
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<td>Insertion trauma</td>
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<tr>
<td>Genital / Perianal Warts</td>
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<tr>
<td>Other Physical evidence</td>
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<tr>
<td>STD (Herpes/chancroid/ulcers)</td>
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<tr>
<td>Non-medical injection sites</td>
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<td>Home produced tattoo</td>
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<td>Recent tattoo</td>
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<td>Recent body piercing</td>
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<tr>
<td>Enlarged lymph nodes</td>
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<tr>
<td>Oral thrush</td>
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<tr>
<td>Blue Purple Spots / Lesions</td>
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<tr>
<td>Trauma / infection</td>
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<tr>
<td>Fever / Rash</td>
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<tr>
<td>Jaundice / Icterus</td>
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<tr>
<td>Enlarged liver (hepatomegaly)</td>
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<tr>
<td>Scabs / Smallpox</td>
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<tr>
<td>Eczema Vaccinatum</td>
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<tr>
<td>Vaccinia necrosum</td>
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<tr>
<td>Corneal scarring</td>
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<tr>
<td>Swollen Eyelids</td>
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</tbody>
</table>
DONOR PHYSICAL ASSESSMENT FORM

Directed Donor Name______________________________________________________________

Key to schematics:

(A) Abrasion  (J) Organ recovery site
(B) Blood draw site  (K) Rash
(C) Body Piercing - requires description and (L) Scar (surgical / trauma)
    date of application.
(D) Bruise / Contusion  (M) Skin Lesion
(E) Dressing / Bandage  (N) Tattoo – requires description and date of application
(F) Fracture / Dislocation  
(G) Hematoma  
(H) Laceration / Wound  
(I) Needle entry site  

Authorized person completing the initial physical examination:

__________________________________________
Print

__________________________________________
Signature

______________________________
Date