Directed Donor Banking Program (Sperm)

The UI Health Andrology Laboratory offers this program for
those who are interested in using a Directed (Known) Donor, such as a relative, close friend, and our transgender friends for assisted reproductive procedures.

Specifically, The UI Health Andrology Laboratory offers this program to:

1) Clients who are interested in using a Directed (i.e. known) Donor to achieve a pregnancy.
2) Clients who wish to use their sperm specimens with a non- sexually intimate individual to achieve a pregnancy.

Directed Semen Donor Eligibility Requirements

Directed 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 following is required to be an eligible directed donor:

1) Testing for communicable disease (see requirements and time frame below)

2) Completion of an FDA Medical History Questionnaire (provided by Lab)

3) Completion of a required physical exam and medical evaluation (see requirements below)

Specimens cannot be released with a Donor Eligibility Determination Form until all documentation from numbers 1-3 are received.

Testing for Communicable Diseases

- Testing must be done using **ViroMed Laboratories (Donor Screening Panel # 139496)**. **LabCorp** testing centers offer this service. If a ViroMed kit is not used, donor eligibility determination will not be done.

- **TESTING MUST BE COMPLETED WITHIN 7 DAYS OF EACH SEMEN COLLECTION (7 days before or by 7 days after each semen collection)**

1. HIV, type 1 **and** HIV-1 NAT (nucleic acid amplification test method)
2. HIV, type2
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 gonorrhea
10. West Nile Virus NAT

- Copies of these lab test results must be submitted to the Andrology Lab and the physician performing physical medical exam.

- Semen specimens will be held in the quarantine tank until all communicable disease 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.

Medical Evaluation and Physical Exam

- Directed Donors must complete an FDA Medical History Questionnaire provided by the UIC Andrology Lab (download on website). One copy must be returned to the Andrology Lab and one copy provided to the physician performing a physical exam and evaluation.
- Directed Donors must complete a physical exam and medical evaluation with a physician. If you do not have one, we will refer you to a doctor at UI Health.
    - Provide the physician with the ViroMed (LabCorp) test results for communicable diseases and the completed Medical Questionnaire (above) for evaluation.
    - A physical exam for evaluation of communicable disease is to be completed by the physician. (A form for this exam can be downloaded on our website).
    - Have physician complete this form and sign both the Medical Questionnaire and the Physical Exam form.
- Return both forms to the UI Andrology Lab.

Please Keep in Mind

The UI Health Donor Banking Program is responsible for the processing, storage, and distribution of semen from directed donors. We are not responsible for all the phases of testing.

If you are interested in banking as a Directed Donor, please contact our coordinator at 312-996-7713.

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.

Zika Virus Screening Questionnaire	
Physician's Name	
Directed Semen Donor's Name	

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

Physician's Signature **Date**

Department of Urology (MC955)
University Andrology Laboratory
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Chicago, Illinois 60612-7316

T 312-996-7713
F 312-996-1291
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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 had sex in the preceding 12 months with any person described in the previous 4 items of this section or with any person known or suspected to have HIV infection, including a positive or reactive test for HIV virus, hepatitis B infection, or clinically active (symptomatic) hepatitis C infection?

____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.**

Directed Donor Name_____

____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/ncidod/sars/index.htm) 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

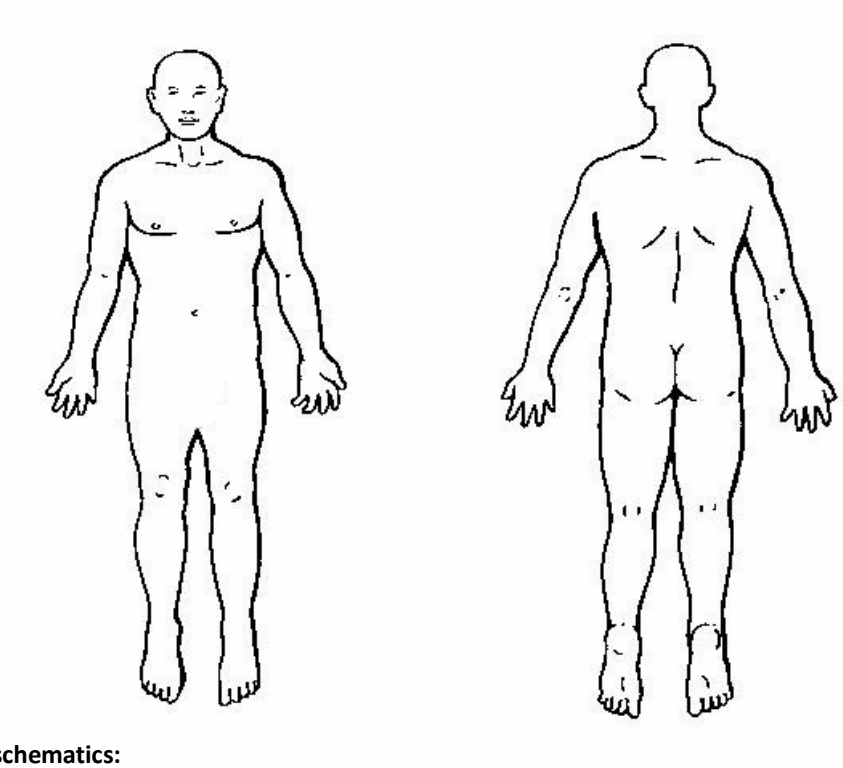
PHYSICAL ASSESSMENT

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

Poor Basic Hygiene	_____ yes	_____ no	_____ comments
Genital lesions	_____ yes	_____ no	_____ comments
Insertion trauma	_____ yes	_____ no	_____ comments
Genital / Perianal Warts	_____ yes	_____ no	_____ comments
Other Physical evidence	_____ yes	_____ no	_____ comments
STD (Herpes/chancroid/ulcers)	_____ yes	_____ no	_____ comments
Non-medical injection sites	_____ yes	_____ no	_____ comments
Home produced tattoo	_____ yes	_____ no	_____ comments
Recent tattoo	_____ yes	_____ no	_____ comments
Recent body piercing	_____ yes	_____ no	_____ comments
Enlarged lymph nodes	_____ yes	_____ no	_____ comments
Oral thrush	_____ yes	_____ no	_____ comments
Blue Purple Spots / Lesions	_____ yes	_____ no	_____ comments
Trauma / Infection	_____ yes	_____ no	_____ comments
Fever / Rash	_____ yes	_____ no	_____ comments
Jaundice / Icterus	_____ yes	_____ no	_____ comments
Enlarged liver (hepatomegaly)	_____ yes	_____ no	_____ comments
Scabs / Smallpox	_____ yes	_____ no	_____ comments
Eczema Vaccinatum	_____ yes	_____ no	_____ comments
Vaccinia necrosum	_____ yes	_____ no	_____ comments
Corneal scarring	_____ yes	_____ no	_____ comments
Swollen Eyelids	_____ yes	_____ no	_____ comments

DONOR PHYSICAL ASSESSMENT FORM

Directed Donor Name_____



Key to schematics:

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

Authorized person completing the initial physical examination:

_____
Print

_____ _____
Signature Date