Health Canada Santé Canada

Draft Health Canada Directive:

Technical Requirements for Conducting the Suitability Assessment of Sperm and Ova Donors

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Canada

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Ébauche de la directive de Santé Canada : Exigences techniques concernant l'évaluation de l'admissibilité du donneur de spermatozoïdes ou d'ovules

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A. Preface

The purpose of the Health Canada Directive entitled ***Technical Requirements for Conducting the Suitability Assessment of Sperm and Ova Donors*** (Directive) is to reduce the risks to human health and safety. The Directive outlines the minimum requirements for screening, testing and conducting the suitability assessment of sperm and ova donors to reduce the risk of disease transmission from the donor to the recipient and the child born from the use of assisted human reproduction.

B. List of abbreviations

ABO	ABO blood group system
CJD	Creutzfeldt-Jakob disease
CMV	Cytomegalovirus
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HTLV	Human T-cell Lymphotropic Virus
IgG	Immunoglobulin G
IgM	Immunoglobulin M
NAT	Nucleic Acid Testing
Rh	Rhesus factor
WNV	West Nile Virus
ZIKV	Zika Virus

C. Definitions

Autosomal dominant disease: Autosomal dominant disease is monogenetic inherited disease caused by a mutant copy of the disease-associated gene.

Autosomal recessive disease: Autosomal recessive disease is monogenetic inherited disease that occurs only in individuals with two mutant copies of the disease-associated gene.

Medical Director: Medical director in respect of a primary establishment, means a person who is authorized under the laws of the jurisdiction in which the primary establishment is situated to practice the profession of medicine and who is responsible for all medical and technical procedures carried out during the processing of sperm or ova.

X-linked disease: It is a monogenetic inherited disease caused by a mutant copy of the disease-associated gene located on the X chromosome.

D. Donor suitability

1. General

A donor suitability assessment must be conducted and documented by the Medical Director or a physician designated by the Medical Director and must be based on the following:

a. donor screening in accordance with Clause 2.1;
b. physical examination of the donor in accordance with Clause 2.2; and
c. donor testing in accordance with Clause 2.3.

2. Donor suitability assessment

2.1. Donor screening

A sperm or ova donor must be screened using a structured questionnaire to obtain the donor's relevant information, including their age at the time of obtaining the sperm or ova; donor's medical history to identify indications of high risk for infectious disease transmission, including the risk of emerging disease/s; and their genetic history to identify the risk of genetic disease transmission.

2.1.1. Infectious disease screening

I. The infectious disease screening must be conducted using a structured questionnaire, prepared by the Medical Director or a physician designated by the Medical Director.

II. The structured questionnaire to assess the donor's risk of infectious disease transmission must include the following screening criteria:

a. person with a diagnosis of Spongiform encephalopathy or prion-related disease, including but not limited to a diagnosis of CJD, or first-degree family member with history of CJD;

b. recipient of human growth hormone within the following time frames:

1. prior to 1986, if the treatment took place in Canada or the United States (US); or
2. if the treatment took place in a country other than Canada or the US, any time that human-derived pituitary growth hormone was available for therapeutic use in that country.

c. recipient of dura mater;

d. person with active encephalitis or meningitis of infectious or unknown etiology;

e. person with a diagnosis of dementia or any degenerative or demyelinating disease of the central nervous system or other neurological disease of unknown etiology;

f. person who has been treated for or had *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, or *Treponema pallidum* infection in the preceding 12 months. If infection and treatment occurred more than 12 months ago, evidence of successful treatment such as negative test result must be documented;

g. person with a diagnosis of active genital herpes by history, and/or physical examination;

h. person with urethral discharge, genital warts, or genital ulcers at the time of donation;

i. person with infections of clinical significance;

j. person with any major systemic disorder, including systemic malignancies which might compromise the gamete;

k. person who has had a diagnosis or suspicion of WNV infection (based on symptoms and/or laboratory results or confirmed WNV viremia) in the preceding 120 days following diagnosis or onset of illness, whichever is later;

l. person who within the past six months: (i) has been diagnosed with ZIKV infection; (ii) has resided in, or travelled to, an area with ZIKV transmission; or (iii) has had sex with a man who is known to have either of the risk factors listed in (i) or (ii) above;

m. In the case where the sperm donor is subject to the Regular Process requirements, indications of high risk for HIV, HBV, HCV, or HTLV, including:

1. person who reports nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the last 5 years;

2. a man who has had sex with a man in the preceding six months;

3. person who has engaged in sex in exchange for money or drugs in the preceding six months;

4. person who has had sex in the preceding six months with any person described in Items (m1) to (m3), or with a person known to have HIV, or clinically active HBV or clinically active HCV;

5. person who has been exposed, in the preceding six months, to known or suspected HIV-, HBV-, and/or HCV-infected blood through percutaneous inoculation or through contact with an open wound, non-intact skin, or mucous membrane;

6. person who has been in a youth correctional facility, jail, or prison for more than 72 consecutive hours in the preceding six months;

7. person who in the preceding six months, has undergone tattooing, ear piercing, or body piercing in which sterile procedures were not used;

8. person who in the preceding six months, has had close contact with another person having clinically active HBV or clinically active HCV infection;

9. person with a history of infection with HIV-1, HIV-2, HTLV-1, HTLV-2, clinically active HBV or clinically active HCV; and

10. person who in the preceding six months has received, or whose sexual partner(s) has received, blood, blood components, blood products, or other human tissues that are known to be possible sources of blood-borne pathogens, unless approved by the Medical Director in conformance with generally accepted standards of practice.

n. In the case where the ova donor is subject to the Regular Process requirements and the donor is not required to be retested, indications of high risk for HIV, HBV, HCV, or HTLV, including:

1. person who reports nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the last 5 years;

2. person who has engaged in sex in exchange for money or drugs in the preceding 12 months;

3. person who has had sex in the preceding 12 months with: any person described in Items (n1) and (n2); a man who has had sex with a man in the preceding 12 months; or a person known to have HIV, or clinically active HBV or clinically active HCV;

4. person who has been exposed, in the preceding 12 months*, to known or suspected HIV-, HBV-, and/or HCV-infected blood through percutaneous inoculation or through contact with an open wound, non-intact skin, or mucous membrane;

5. person who has been in a youth correctional facility, jail, or prison for more than 72 consecutive hours in the preceding 12 months;

6. person who in the preceding 12 months*, has undergone tattooing, ear piercing, or body piercing in which sterile procedures were not used;

7. person who in the preceding 12 months, has had close contact with another person having clinically active HBV or clinically active HCV infection;

8. person with a history of infection with HIV-1, HIV-2, HTLV-1, HTLV-2, clinically active HBV or clinically active HCV;

9. person who in the preceding 12 months has received, or whose sexual partner(s) has received, blood, blood components, blood products, or other human tissues that are known to be possible sources of blood-borne pathogens, unless approved by the Medical Director in conformance with generally accepted standards of practice; and

10. person with a history of intranasal cocaine use in the last six months, unless HCV NAT is performed and found to be negative.

* The 12 month period specified in items (n4) and (n6) above may be reduced to six months if NAT is used for the detection of HIV, HBV, and HCV.

o. In the case where the sperm or ova donor is subject to the Directed Donation Process requirements and the donor is not required to be retested, indications of high risk for HIV, HBV, HCV, or HTLV, including:

1. person who reports nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the last 5 years;

2. a man who has had sex with a man in the preceding 12 months (sperm donor only);

3. person who has engaged in sex in exchange for money or drugs in the preceding 12 months;

4. person who has had sex in the preceding 12 months with any person described in Items (o1), (o2), and (o3), or with a person known to have HIV, or clinically active HBV or clinically active HCV;

5. person who has been exposed, in the preceding 12 months*, to known or suspected HIV-, HBV-, and/or HCV-infected blood through percutaneous inoculation or through contact with an open wound, non-intact skin, or mucous membrane;

6. person who has been in a youth correctional facility, jail, or prison for more than 72 consecutive hours in the preceding 12 months;

7. person who in the preceding 12 months*, has undergone tattooing, ear piercing, or body piercing in which sterile procedures were not used;

8. person who in the preceding 12 months, has had close contact with another person having clinically active HBV or clinically active HCV infection;

9. person with a history of infection with HIV-1, HIV-2, HTLV-1, HTLV-2, clinically active HBV or clinically active HCV;

10. person who in the preceding 12 months has received, or whose sexual partner(s) has received, blood, blood components, blood products, or other human tissues that are known to be possible sources of blood-borne pathogens, unless approved by the Medical Director in conformance with generally accepted standards of practice; and

11. persons with a history of intranasal cocaine use in the last six months, unless HCV NAT is performed and found to be negative.

* The 12 month period specified in items (o5) and (o7) above may be reduced to six months if NAT is used for the detection of HIV, HBV, and HCV.

2.1.2. Genetic disease screening

I. The genetic disease screening must be conducted using a structured questionnaire prepared by the Medical Director or a qualified professional designated by the Medical Director.

II. The structured questionnaire to assess the risk of genetic disease transmission must include the following genetic disease screening criteria:

(a) presence of a serious autosomal dominant, autosomal recessive, or X-linked genetic disorder in the sperm or ova donor; and

(b) presence of a serious autosomal dominant, autosomal recessive, or X-linked genetic disorder in three generations of the sperm or ova donor's family genetic history.

III. In lieu of performing the genetic disease screening set out in Clause 2.1.2 (I) and (II), the results of the relevant genetic testing of the sperm or ova donor for the presence of one or more serious autosomal dominant, autosomal recessive, or X-linked genetic disorders, performed in accordance with Clause 2.3.1 (II), may be used to assess the donor for the risk of genetic disease transmission.

IV. Based on the results of the genetic disease screening, an assessment of the risk of genetic disease transmission must be carried out by the Medical Director or a qualified professional designated by the Medical Director and the results of the assessment must be documented.

2.2. Physical examination

A physical examination of a sperm or ova donor must be performed by the Medical Director or a physician designated by the Medical Director. The results of a physical examination conducted within the previous six months, where indications of high-risk for infectious or genetic disease transmission were assessed, can be reviewed and documented in lieu of a new physical examination.

2.3. Donor testing

2.3.1. General

I. Each establishment engaged in conducting donor testing must develop Standard Operating Procedures (SOPs) that describe all infectious disease tests to be performed and the handling of positive and indeterminate test results.

II. Testing must be performed:

a. using appropriate and effective test methods;

b. by a laboratory that meets the accreditation requirements of the province in which the laboratory is located, or, in the case of imported sperm or ova, by a laboratory that meets a recognized equivalent accreditation requirement;

c. using screening or diagnostic test kits that are licensed:
   i. in Canada, if the testing is performed in Canada; or
   ii. in Canada or the US, if the testing is performed outside Canada.

d. in accordance with the manufacturer's requirements for specimens, and the manufacturer's instructions for the performance of the test and interpretation of test results.

III. A sperm donor must be tested for the infectious disease agents set out in Clause 2.3.3 (I) (a), (b), (c), (d), (f), and (g) using donor screening test kits.

IV. An ova donor must be tested for the infectious disease agents set out in Clause 2.3.3 (I) (a), (b), (c), and (g) using donor screening test kits.

V. A sperm or ova donor must be tested for the infectious disease agents set out in Clause 2.3.3 (I) (e), (h), and (i) using either donor screening test kits or diagnostic test kits.

VI. If a licensed test kit for the infectious disease agents set out in Clause 2.3.3 (I) (h) and (i) is unavailable for the specimen being tested, the laboratory must have validation data to support the use of the test method for the intended application.

VII. The ABO and Rh status of a sperm or ova donor must be determined at either the initial testing stage or any time prior to the release of the sperm or ova from quarantine.

2.3.2. Timing of specimen collection

I. A sperm donor must be tested for the infectious disease agents set out in Clause 2.3.3 (I), using specimen collected within seven days of obtaining the sperm sample. In the case of a sperm donor from whom a specimen has already been collected and for whom retesting is required under Clause E, it is not required to collect a specimen at the time of each donation.

II. An ova donor must be tested for the infectious disease agents set out in Clause 2.3.3 (I), except 2.3.3 (I) (d) and (f), using specimen collected within 30 days before obtaining ova or within seven days of obtaining ova.

2.3.3. Infectious disease agents

I. A sperm or ova donor must be tested for the following infectious disease agents:

a) HIV-1 and 2;
b) HCV;
c) HBV;
d) HTLV-I and HTLV-II (sperm donor only);
e) *Treponema pallidum* (syphilis)
    i. non-treponemal test; or
    ii. treponemal-specific test.
f) CMV (sperm donor only);
g) WNV, if the donation is made during the time of year when WNV is potentially transmissible to humans in the donor's country of residence, or if in the preceding 56 days, a donor has lived in or travelled to an area where WNV is endemic;
h) *Chlamydia trachomatis*; and
i) *Neisseria gonorrhoeae*.

3. Donor reassessment

3.1. Reassessment of sperm donors

3.1.1. In the case of a repeat sperm donor subject to the Regular Process requirements, screening must be conducted every six months, or after any lapse exceeding six months, on the basis of the donor screening criteria set out in Clause 2.1.

3.1.2. In the case of a repeat sperm donor subject to the Regular Process requirements, a physical examination must be conducted every six months or after any lapse exceeding six months, in accordance with the physical examination requirements set out in Clause 2.2.

3.1.3. In the case of a repeat sperm donor subject to the Regular Process requirements, testing for infectious disease agents set out in Clause 2.3.3 (I) (h) and (i) must be performed every six months or after any lapse exceeding six months, in accordance with the donor testing requirements set out in Clause 2.3.1(I) to (III), (V) and (VI).

3.1.4. In the case of a repeat sperm donor where the donor is subject to the Directed Donation Process requirements, a physical examination must be conducted every six months or after any lapse exceeding six months, in accordance with the physical examination requirements set out in Clause 2.2.

3.1.5. In the case of a repeat sperm donor where the donor is subject to the Directed Donation Process requirements, the donor screening and testing must be performed every three months or after any lapse exceeding three months, in accordance with the requirements set out in Clauses 2.1 and 2.3, respectively.

3.2. Reassessment of ova donors

3.2.1. In the case of a repeat ova donor, screening on the basis of the donor screening criteria set out in Clause 2.1 must be conducted at the time of each donation.

3.2.2. In the case of a repeat ova donor, a physical examination in accordance with the physical examination requirements set out in Clause 2.2 must be performed at the time of each donation.

3.2.3. In the case of a repeat ova donor, testing for infectious disease agents set out in Clause 2.3.3 (I) must be conducted in accordance with the donor testing requirements set out in Clauses 2.3.1(I), (II), (IV) to (VI) and 2.3.2, at the time of each donation.

4. Donor exclusion

A sperm or ova donor, except for a donor who is subject to the Directed Donation Process requirements, who meets any of the following donor exclusion criteria must be determined unsuitable:

a. A sperm or ova donor who meets any of the infectious disease screening criteria set out in Clause 2.1.1 (II) (a) to (n).

b. A sperm or ova donor who is symptomatic or has previously been diagnosed with a serious autosomal dominant or X-linked genetic disorder.

c. With the exception of *Treponema pallidum* and CMV, a sperm or ova donor who tests positive for any of the infectious disease agents listed in Clause 2.3.3 (I). Sperm samples obtained between testing intervals in which infection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* cannot be ruled out shall be discarded.

d. In the case of *Treponema pallidum*, a sperm or ova donor who tests positive for *Treponema pallidum* using the treponemal-specific test. A sperm or ova donor may be determined suitable if the non-treponemal test is negative or positive, but the treponemal-specific test is negative.

e. In the case of CMV, a sperm donor who tests positive for CMV IgM until they become IgM negative. A sperm donor may be determined suitable if the CMV IgG test is negative or positive, but the CMV IgM test is negative.

f. A sperm or ova donor, who has been determined unsuitable due to a positive test result, as specified in Clauses 4(c) and 4(d), may be determined to be suitable if a confirmatory or supplemental test result is negative, and the donor is retested according to an appropriate donor re-entry algorithm.

E. Donor retesting

1.1. A sperm donor who is subject to the Regular Process requirements must be retested for the infectious disease agents set out in Clause 2.3.3 (I) (a) to (f), using a new specimen collected from the donor at least 180 days after the date of donation, in accordance with the donor testing requirements set out in Clause 2.3.1 (I) to (III), (V) and (VI).

1.2. With the exception of *Treponema pallidum* (set out in Clause E.1.2.1) and CMV (set out in Clause E.1.2.2), the retesting results as per Clause E.1.1 must be negative in order to meet the retesting requirement for release from quarantine.

1.2.1. In the case of *Treponema pallidum*, the non-treponemal test can be negative or positive, but the treponemal-specific test must be negative.

1.2.2. In the case of CMV, the CMV IgG test can be negative or positive, but the CMV IgM test must be negative.