Appendix I

Guidelines for Screening of Potential Gamete/Embryo Donors and Recipients Against Infectious Diseases

1. The following guidelines for screening potential gamete/embryo donors and recipients aim at decreasing the potential hazard of transmission of infectious diseases through gamete/embryo donation. They are modified from the "2008 Guidelines for Gamete and Embryo Donation" issued by the American Society for Reproductive Medicine. Modifications are required because local conditions differ.

Guidelines for Screening Potential Semen Donor

2. The main purposes of these guidelines are to decrease the potential hazard for transmitting infectious agents by the use of frozen semen samples that have been adequately quarantined.

Medical History

3. The donors should be generally healthy and in general give no history to suggest hereditary and familial diseases.

4. A complete sexual history should be obtained to exclude as donors individuals who might be at high risk for HIV and/or who have multiple sex partners.

Physical Examination

5. The donor should have a complete physical examination including evaluation for urethral discharge, genital warts and genital ulcers, as well as routine laboratory screening, including blood group and Rh factor testing, before enlisting him in the programme.

6. Donor should have follow-up examinations for urethral discharge, genital warts, and genital ulcers and not be utilised if any of these findings are present.

Laboratory Screening

7. There is no absolute method of completely ensuring that infectious agents will not be transmitted by donor insemination, but the following guidelines, in addition to adequate history-taking and exclusion of individuals at high risk for HIV, should minimise the risk. The following serological tests should be performed -

(a) serologic tests for syphilis should be obtained initially on blood serum and need not be repeated unless clinically indicated;
(b) serum hepatitis B surface antigen (HBsAg), hepatitis B core antibody (anti-HBc) (immunoglobulin G (IgG) and immunoglobulin M (IgM)) and hepatitis C antibody should be tested initially and at 6-month intervals;
(c) semen, urine or urethral cultures should be obtained initially for *Neisseria gonorrhoeae*. Either urethral or urinary testing for *Chlamydia trachomatis* should be performed. These cultures should be repeated at 6-month intervals or more frequently if clinically indicated;
(d) serum antibody tests (IgG and IgM) for CMV should be obtained -

(i) if the antibody tests are positive for active infection, the semen sample should not be used;
(ii) if the antibody tests are positive without active infection, it is suggested that the donor should only be used with recipients who are CMV-positive;
(iii) if the titers are negative, the donor should have CMV titers done at 6-month intervals; quarantined semen samples should not be released if the donor develops an antibody titer suggesting recent CMV infection;
(iv) the donor should also be monitored for any development of heterophil-negative mononucleosis-type illness;

(e) an initial serum screening for HIV antibodies should be performed -
(i) a positive assay should be verified with a Western Blot test before notifying the potential donor;
(ii) if the test is negative, semen samples may be collected and prepared for cryopreservation;
(iii) the donor should be tested again in 180 days for HIV, and the specimen should be released for use only if the results are negative; and

(f) haematological tests on MCV screening for thalassaemia should be performed initially. Patients with low MCV should be subject to Haemoglobin pattern test.

Guidelines for Screening Potential Egg Donors

8. The main purposes of these guidelines are to decrease the potential hazard for transmitting infectious agents by the use of donated eggs.

Medical History

9. The donors should be generally healthy and in general give no history to suggest hereditary and familial diseases.

10. A complete sexual history should be obtained to exclude as donors individuals who might be at high risk for HIV and/or who have multiple sex partners.

Physical Examination

11. The donor should have a complete physical examination including evaluation for urethral discharge, genital warts and genital ulcers, as well as routine laboratory screening, including blood group and Rh factor testing, before enlisting her in the programme. If the use of donor eggs creates the potential of an Rh incompatibility, couples should be informed about the obstetrical significance of this condition.

12. Donor should have follow-up examinations for urethral discharge, genital warts, and genital ulcers and not be utilised if any of these findings are present.

Laboratory Screening

13. There is no absolute method of completely ensuring that infectious agents

will not be transmitted via egg donation, but the following guidelines, in addition to adequate history-taking and exclusion of individuals at high risk for HIV, should minimise the risk. The following serological tests should be performed -

(a) serologic tests for syphilis should be obtained initially on blood serum and need not be repeated unless clinically indicated;
(b) serum hepatitis B surface antigen (HBsAg), hepatitis B core antibody (anti-HBc) (immunoglobulin G (IgG) and immunoglobulin M (IgM)) and hepatitis C antibody should be tested initially and at 6-month intervals;
(c) Cervical cultures on urine or a swab obtained from the cervix, urethral meatus, or vagina for *Neisseria gonorrhoeae* and *Chlamydia trachomatis*. These cultures should be repeated at 6-month intervals or more frequently if clinically indicated;
(d) serum antibody tests (IgG and IgM) for CMV should be obtained -
    (i) if the antibody tests are positive for active infection, the donated eggs should not be used;
    (ii) if the antibody tests are positive without active infection, it is suggested that the donor should only be used with recipients who are CMV-positive;
    (iii) if the titers are negative, the donor should have CMV titers done at 6-month intervals;
    (iv) the donor should also be monitored for any development of heterophil-negative mononucleosis-type illness;
(e) an initial serum screening for HIV antibodies should be performed -
    (i) a positive assay should be verified with a Western Blot test before notifying the potential donor;
    (ii) the donor should be tested again in 180 days for HIV; and
(f) haematological tests on MCV screening for thalassaemia should be performed initially. Patients with low MCV should be subject to Haemoglobin pattern test.

Use of fresh eggs

14. Fresh eggs should only be used after adequate counselling to the recipients about the risk of possible transmission of infectious diseases. The donor must have been screened negative for HIV status before the donation. In addition, hepatitis C nucleic acid test and HIV nucleic acid test are advisable in every donation involving the use of fresh eggs.

Freezing and quarantining of donated eggs or embryos fertilized from donor eggs

15. Fresh eggs should normally be used unless there are situations making the use of frozen eggs necessary.

16. In case donated eggs are frozen, they should be quarantined for at least 180 days before being used for fertilization.

17. Couples entering an egg donation arrangement should be -

(a) informed that the use of fresh eggs for fertilization carries a risk, albeit a low risk, of acquiring HIV;

(b) asked whether they are willing to assume such risk;
(c) asked whether, alternative to (a) above and in order to avoid the said risk, they would like to have the donated eggs fertilized, the resulting embryos frozen and quarantined, and the donor recalled and retested for HIV 6 months after donation before undergoing embryo transfer; and
(d) asked whether they would like to use frozen eggs if there are situations making the use of frozen eggs necessary.

Guidelines for Screening Embryo Donors

18. The respective donors of the sperm and the egg in embryo donation should undergo screening according to the guidelines described in paras. 2-17 above.

Guidelines for Screening Recipients Undergoing Treatment Involving Donation

19. As a best practice, the recipient is advisable to undergo the same screening tests for infectious diseases as the donor, as mentioned in paras. 7 and 13 above.