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16.02.07 - CONTROL OF ANATOMICAL PARTS INTENDED FOR TRANSPLANTING OR TRANSFUSION

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**IDAPA 16
TITLE 02
Chapter 07**

**16.02.07 - CONTROL OF ANATOMICAL PARTS INTENDED FOR
TRANSPLANTING OR TRANSFUSION**

000. LEGAL AUTHORITY.

The Director of the Department of Health and Welfare is directed under Section 39-3703, Idaho Code, to adopt rules concerning the testing of anatomical parts and donors for human immunodeficiency virus infection and the use of anatomical parts for transplanting or transfusion. (3-24-89)

001. TITLE AND SCOPE.

These rules shall be known as Idaho Department of Health and Welfare Rules, IDAPA 16.02.07, "Control of Anatomical Parts Intended for Transplanting or Transfusion". These rules include the criteria for the testing of anatomical parts or the donors of anatomical parts intended for transplanting, implanting or transfusion into another human. (3-24-89)

002. PURPOSE.

The purpose of these rules is to assure that anatomical parts, including whole blood, plasma, blood products, blood derivatives, body tissues, organs, human milk, semen, ova and embryos, are tested or the donors of such parts are tested for evidence of human immunodeficiency virus (HIV) infection prior to transplanting or transfusion into another human. Autologous blood or other tissues obtained for use in the same person are not included in this chapter. (12-31-91)

003. DEFINITIONS.

01. Anatomical Parts. Human body tissues and fluids. (3-24-89)
02. Blood Products. Whole blood or components derived from whole blood and intended for use in another human. (3-24-89)
03. Certificate. Any laboratory report, form or other written or printed statement which can be identified as to its source, containing the results of HIV tests on the donor or a statement that HIV tests are in process while the organ or tissue is enroute. (3-24-89)
04. Department. The Idaho Department of Health and Welfare. (3-24-89)
05. Director. The Director of the Department of Health and Welfare or designated individual. (12-31-91)
06. FDA. Federal Food and Drug Administration. (3-24-89)
07. Human Immunodeficiency Virus (HIV). The virus causing HIV infection, leading to the disease called Acquired Immune Deficiency Syndrome (AIDS). (3-24-89)
08. Human Milk. The fluid secreted from human mammary glands that is intended for consumption by infants. (3-24-89)
09. Negative Test for HIV. No detectable HIV antibody or antigen by an approved testing procedure. (3-24-89)
10. Solid Tissue. An aggregation of similarly specialized cells united in the performance of a particular function. (3-24-89)
11. Transfusion. The introduction into the body of whole blood, blood products or fluids obtained from another person. (3-24-89)
12. Transplantation. The grafting of tissues taken from another human body. (3-24-89)

004. TESTING.

01. Testing of Donor. The donor of any solid tissue, blood, blood products, semen, ova or embryo shall be tested for HIV infection prior to the actual transplant or transfusion of the anatomical parts into another human. (3-24-89)

02. Approved Tests. Only tests approved by the Food and Drug Administration (FDA) or the Director of the state public health laboratory for the purpose of testing anatomical parts or donors of anatomical parts for the evidence of HIV infections shall be used. (3-24-89)

03. Test Results. All positive test results for HIV antibody or antigen shall be reported to the Department or District Health Department as required in Section 39-606, Idaho Code. (3-24-89)

005. STORAGE OF ANATOMICAL PARTS.

All licensed, accredited or approved facilities that store human bodies or anatomical parts intended for transplanting into another human must register annually with the Director. The registration shall consist of a description of the tissue storage activities including the types of tissues stored, the approximate number of tissues stored and a certification that tissues will not be supplied for transplantation or transfusion unless the anatomical part or the donor of the anatomical part has tested negative for HIV antibodies or antigens as required by Sections 39-3403 and 39-3703, Idaho Code. (3-24-89)

006. BLOOD AND BLOOD PRODUCTS.

01. Blood Tests. All blood and blood products intended for transfusion into another human must test negative for HIV antibody and/or antigen as required by applicable federal statutes, FDA regulations and Section 39-3703, Idaho Code. (3-24-89)

02. Blood Storage. All facilities within Idaho which store, for any length of time, blood or blood products intended for transfusion into humans must register annually with the Director. The registration shall consist of a description of the blood products collected or processed and a certification that all units of blood products are tested for HIV antibody and/or antigen prior to transfusion into another human. (3-24-89)

03. Blood From Out-of-State. No blood or blood products intended for use in humans may be shipped into Idaho unless the manufacturer or processor of the blood or blood products can certify that the product has tested negative for HIV antibody and/or antigen. (3-24-89)

04. Test Results -- Records, Reports. Records of HIV test results shall be made available to the Department upon request from the Director. All positive test results shall be reported in accordance with Section 39-602, Idaho Code. (3-24-89)

007. SOLID TISSUES.

01. Solid Tissue Tests. All donors of solid tissues that are harvested in Idaho must be tested for HIV infection using an approved procedure. The HIV tests must be completed prior to the transplanting of the solid tissue into another human. (3-24-89)

02. Solid Tissue From Out-of-State. No solid tissue may be shipped into Idaho unless the tissue is accompanied by a certificate that the donor of the tissue has tested negative for HIV infection using a test that has been approved for this purpose. (3-24-89)

03. Solid Tissue Standards. Current standards of practice recommended by the American Association of Tissue Banks shall be followed by all facilities that harvest, store or transplant solid tissues in Idaho. (3-24-89)

04. Test Results -- Records, Reports. Records of HIV test results shall be made available to the Department upon request from the Director. All positive test results shall be reported in accordance with Section 39-602, Idaho Code. (3-24-89)

008. HUMAN MILK.

01. Human Milk Tests. All donors of human milk must be tested for HIV infection using an approved procedure if the human milk is intended for consumption by a child other than her own child. (3-24-89)
02. Blood Samples. A blood sample must be taken from the donor and tested for HIV antibody or antigen at the time human milk is donated. The human milk may be frozen and a second blood sample from the donor taken not less than ninety (90) days after donating the human milk. Both blood samples must test negative before the human milk can be released for human use. (3-24-89)
03. Human Milk From Out-of-State. No human milk may be shipped into Idaho unless the donor of the human milk has tested negative for HIV antibody or antigen. (3-24-89)
04. Human Milk Storage. All facilities which store human milk must register with the Department and certify that no human milk shall be released for consumption by infants unless the donor has tested negative for HIV antibody or antigen at least ninety (90) days following the donation of the human milk. (3-24-89)
05. Test Results -- Records, Reports. Records of HIV test results shall be made available to the Department upon request of the Director. All positive test results shall be reported in accordance with Section 39-602, Idaho Code. (3-24-89)

009. SEMEN, OVA, EMBRYOS.

01. Semen Use. Fresh semen may be used for artificial insemination only when the donor is involved in a mutually monogamous marriage or relationship with the recipient. Artificial insemination shall not be performed without prior written request and consent of the woman and man as required by Section 39-5403, Idaho Code. (3-24-89)
02. Semen Storage -- Blood Samples. Semen that will not be used within two (2) hours must be frozen prior to use for artificial insemination. A blood sample must be taken from the donor and tested for HIV antibody or antigen at the time semen is donated. A second blood sample from the donor taken not less than ninety (90) days after donating the semen must also be collected and tested for HIV antibody or antigen. Both blood samples must test negative before semen can be released for human use. (3-24-89)
03. Semen From Out-of-State. No semen may be shipped into Idaho unless the donor of the semen has tested negative for HIV antibody or antigen. (3-24-89)
04. Physician Registration -- Use of Semen. All physicians who perform artificial insemination using frozen semen must register with the Department and certify that no semen shall be used unless the donor has tested negative for HIV antibody or antigen at least ninety (90) days following the donation of the semen. (3-24-89)
05. Human Ova Test. Nonautologous donors of human ova must test negative for HIV antibody or antigen within seventy-two (72) hours prior to donation. (3-24-89)
06. Physician Registration -- Use of Ova. All physicians who use ova for transplanting into a human body must be registered with the Department and certify that no ova shall be used unless the donor has tested negative for HIV antibody or antigen within seventy-two (72) hours prior to donation. (3-24-89)
07. Semen Donor Test. Before the ova is fertilized with the semen to become an embryo, except as described in Subsection 009.01, the semen donor shall be tested for HIV antibody or antigen as described in Subsection 009.02. (12-31-91)
08. Physician Registration -- Embryo Transplant. All physicians who transplant embryos into a woman must register with the Department and certify that no embryo shall be used unless the nonautologous donors have tested negative for HIV antibody or antigen. (3-24-89)

09. Test Results -- Records, Reports. Records of HIV test results shall be made available to the Department upon request of the Director. All positive test results shall be reported in accordance with Section 39-602, Idaho Code. (3-24-89)

010. -- 994. (RESERVED).

995. INJUNCTION.

Notwithstanding any other remedy at law, the Director may seek an injunction against any person to enjoin the transfusion, transplantation or storage of any anatomical part when such action is in conflict with Title 39, Chapter 34 or 37, Idaho Code, or rules and regulations promulgated under those chapters. (12-31-91)

996. (RESERVED).

997. CONFIDENTIALITY.

Before any information about a patient, client, registrant, applicant or recipient contained in the departmental records may be released to the person who is the subject of the record, to another departmental unit, to another governmental agency or to a private individual or organization, the unit of the Department with custody of the record must comply with Idaho Department of Health and Welfare Rules, IDAPA 16.05.01, "Rules Governing Protection and Disclosure of Department Records". (3-24-89)

998. INCLUSIVE GENDER.

As used in these rules, the masculine, feminine, or neuter gender, and the singular or plural number, will each be deemed to include the others whenever the context so requires. (3-24-89)

999. SEVERABILITY.

Idaho Department of Health and Welfare Rules, IDAPA 16.02.07, "Control of Anatomical Parts Intended for Transplanting or Transfusion," are severable. If any rule, or part thereof, or the application of such rule to any person or circumstance is declared invalid, that invalidity does not affect the validity of any remaining portion of the chapter. (3-24-89)