Healthcare Provider Information Form

Hospital ID Label

Complete and return this form with labeled specimens.

1. BIRTH MOTHER INFORMATION / DONOR VERIFICATION

Name of Birth Mother: (Please print) _____

Maternal Blood Draw on: Date: _____ Time: _____ (Circle one: am / pm)

Has the birth mother received any blood products within 48 hours prior to her blood draw? ❑ YES ❑ NO

Has the birth mother received more than 2000mL of IV fluids within 1 hour prior to her blood draw? ❑ YES ❑ NO

2. BABY'S COLLECTION INFORMATION ❑ Single Birth ❑ Multiple Birth ❑ Surrogate ❑ Adoption

(Check all that apply)

Date: Cord Blood Collection ____/____/____ Time: Cord Blood Collection _____ (Circle one: am / pm)

Date: Cord Tissue Collection ____/____/____ Time: Cord Tissue Collection _____ (Circle one: am / pm)

Type of Delivery: ❑ Vaginal ❑ Cesarean Section Gestational Age: _____weeks

Collection issues or adverse events: _____

(If issues or adverse events notated, they will be reviewed by Cryo-Cell International Medical Director)

IMPORTANT - SIGNATURE REQUIRED FOR PROCESSING

3. TRAINING ACKNOWLEDGEMENT

- I understand and acknowledge that the collection of cord blood/cord tissue shall not jeopardize or put at risk the health of the mother and/or the health of the baby. As the cord blood/cord tissue collector, I acknowledge that complications may occur during delivery which could prevent or impede the collection of the cord blood/cord tissue or produce an inadequate specimen collection.
- A medical history interview and physical examination was completed on the birth mother and baby in accordance to the Physical Exam Guidance provided on the back of this page. I acknowledge that the birth mother and baby are in good health and find no physical evidence of risk for or symptoms of transmissible disease.
- If there were any abnormal or remarkable findings during the current pregnancy or detected during the birth carrier or the baby's physical exam and medical history interview, please describe: _____

  (if left blank, physical exams will be considered within normal limits)
- I have read and comprehend the proper collection techniques and procedures for birth mother's blood, cord blood and cord tissue as addressed in the Healthcare Provider Instructions.

COLLECTION AGREEMENT

I agree to perform the collection per Cryo-Cell International's procedures. I have verified the mother using 2 forms of identification per instructions.

_____ _____

Healthcare Provider Signature Date

_____

Print Healthcare Provider Name

4. PHYSICIAN INFORMATION

What **physician or midwife** is responsible for the collection?

_____

Please make any corrections to the information on the label in the space provided. If label not present, please provide Healthcare Provider information below. (name, office address and phone number)

_____

_____

_____

_____

Baby's Name (please print legibly):

_____

Kit ID (located on the side of the kit):

FOR CRYO-CELL LAB USE ONLY

Comments: _____

_____

_____

Reviewed by: _____ Date: _____

(Initials)

Medical Director Review: _____ Date: _____

(If applicable)

Healthcare Provider Information

PHYSICAL EXAM GUIDANCE

PLEASE NOTE: Physicians are required to complete and verify physical exam on birth mother and baby at time of cord blood collection. Failure to verify physical exam on collection form may result in limitations of future use.

Physical exam should assess any signs that may indicate high-risk behavior for or infection with a relevant communicable disease. Some of the following are not physical evidence of HIV, hepatitis, syphilis, or vaccinia but rather are indications of high-risk behavior associated with these diseases and would increase the donor's relevant communicable disease risk.

For more information on the physical exam requirements, please refer to section F & G from the Guidance for Industry Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).

- Physical evidence for risk of sexually transmitted diseases such as genital ulcerative disease, herpes simplex, chancroid (you should consider these signs in light of other information obtained about the donor in making a donor eligibility determination) (seen in HIV, Hepatitis B virus, Chlamydia trachomatis, and Neisseria gornorrheae).
- Physical evidence for risk of, or evidence of syphilis.
- Physical evidence of nonmedical percutaneous drug use such as needle tracks; your examination should include examination of tattoos, which might be covering needle tracks (seen in HIV, Hepatitis B and Hepatitis C).
- Physical evidence of recent tattooing, ear piercing, or body piercing. Persons who have undergone tattooing, ear piercing, or body piercing in the preceding 12 months, in which sterile procedures were not used (e.g., contaminated instruments and or/ink were used), or instruments that had not been sterilized between uses were used (seen in HIV, Hepatitis B and Hepatitis C).
- Disseminated lymphadenopathy (seen in HIV).
- Unexplained Oral thrush (seen in HIV).
- Blue or purple spots consistent with Kaposi's sarcoma (seen in HIV).
- Unexplained jaundice, hepatomegaly, or icterus (seen in Hepatitis B and Hepatitis C).
- Physical evidence of sepsis, such as unexplained generalized rash or fever.
- Large scab consistent with recent history of smallpox immunization.
- Eczema vaccinatum (seen in vaccinia).
- Generalized vesicular rash (generalized vaccinia).
- Severely necrotic lesion consistent with vaccinia necrosum.
- Corneal scarring consistent with vaccinial keratitis.

ZIKA VIRUS INFORMATION

Due to current information linking Zika virus and possibility for congenital infection and neurologic abnormalities additional risk determination should be made to women who have traveled to areas identified by the CDC as an area with Zika.

This information is updated on the CDC Website: http://www.cdc.gov/zika/geo/index.html as new information is received.

For the woman or their sexual partner who have traveled to or live in Zika transmission areas during the pregnancy, include an exam for the following clinical findings:

- Acute onset of fever with maculopapular rash, arthralgia, or conjunctivitis.
- Myalgia and headache
- Guillain-Barre syndrome

Perform complete exam on infant for the following clinical findings:

- Microcephaly
- Neurologic abnormalities

DONOR IDENTIFICATION

Please confirm the donor using 2 (two) forms of identification, such as any of the following:

- Hospital ID
- Provider labels (pre-enrollment kits only)
- Name
- Date of Birth
- Address
- Government Issued ID

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