



Birth Tissue Donation Information Sheet

When your baby is delivered at one of BTR's participating hospitals, you may allow Birth Tissue Recovery LLC to recover your postnatal tissue (placenta, amniotic membrane, amniotic fluid, chorion, and a portion of the umbilical cord) after the baby's delivery. These birth tissues can be used to treat wounds such as diabetic ulcers or burns, or used to treat damaged eyes. Tissue may also be used to study new treatments, or research the development of other products.

Birth tissue (or afterbirth) is normally discarded after delivery. If you give permission for your afterbirth to be donated and you qualify for participation, the afterbirth will be collected rather than discarded. The collection of the placenta and its attached umbilical cord will take place after delivery, and will not affect the care of you or your baby.

Purpose

The main purpose of birth tissue donation is to provide tissue for the manufacture of wound-healing products. Published medical literature has shown that such tissue can be used to treat patients with various medical conditions or who are undergoing surgery.

Description

To participate, you will be asked to:

- Sign a consent form
- Complete and sign a medical and social history questionnaire
- Allow the review and copying of portions of your medical record
- Allow blood to be drawn and tested

The donation process does not involve an invasive procedure, other than blood sample collection, and the alternative is not to donate the postnatal tissue. Your participation is entirely voluntary.

You will be asked to permit the review and, when necessary to make copies, of your medical record, and to obtain and test a blood specimen to help ensure the safety of tissue for use. A mother qualifies to donate if she does not have any diseases that could be passed on to a patient who receives transplant products made from

the birth tissue. The review of your medical record is strictly confidential, and all information and documents remain private and secure.

All information is kept strictly confidential and no identifying information is shared with anyone, except where required by law. You will complete a medical questionnaire, and our trained and experienced staff will review it with you to help make sure that the tissue is safe for use. This questionnaire is similar to one used for blood donation. When someone volunteers to donate blood they must answer a series of questions to help determine whether they have been exposed to any infectious diseases that might be present in the blood. The questionnaire will be completed during a brief, private interview.

If possible, we will obtain your blood sample at the same time as other specimens that your doctor requests during your routine medical care. This way no extra needle stick is necessary.

Your blood will be tested for several infections that could transmit disease through use of products made from birth tissue. These infectious disease tests are mandated by law whenever blood or tissue is offered for donation.

If necessary, we will report the results of these tests to your physician within 3-4 weeks. Your physician will discuss with you the meaning of these results.

Potential Risks and Discomforts

There are no significant risks related to donating your birth tissues. The amount of blood drawn from you is small and not enough to affect your health. Taking blood from you has a small risk of slight pain and bruising, lightheadedness, possible fainting and, rarely, infection. The donated placenta and portion of the umbilical cord is not needed after your baby is born. Some of the questions included on the donor screening questionnaire are of a personal nature and may cause you to feel embarrassed. You may ask to review the questions before deciding whether to participate.

Potential Benefits

An indirect benefit of participating is that you will be helping others by the production of products that heal wounds or help prevent infection. Or, can be used to develop new beneficial medical devices that help patients.

The birth tissues will not be used to make cosmetics or beauty products.

Confidentiality

Birth Tissue Recovery staff will attach a unique identification code to the donated tissue and the records related to your donation. We will keep the Questionnaire, Consent Form, and any other records that have your identity at the offices of BTR. To protect your privacy, we will keep all information that contains your personal identifiers confidential and in a secure location, with access allowed only to authorized personnel. We will also store all other information we collect about you and all test results in secure electronic records, and allow access only to authorized personnel. We will not transfer any identifying information that would allow linkage to you or your baby. We will not identify you or your baby in any publications.



Costs and Reimbursements

Birth tissues are normally discarded after delivery. There will be no cost to you for any blood test. We will not pay you for the birth tissue donation. Participation is voluntary. Choosing not to participate will not affect your medical care in any way.

Financial Disclosure

Birth Tissue Recovery LLC will provide the tissue to commercial entities for the manufacture of medical products that help wounds heal. If BTR provides tissue to outside centers, then it will be paid for its service.

Questions

You may ask questions at any time during the consent process. Afterward, if you have any questions about donating birth tissues or Birth Tissue Recovery LLC you may contact Birth Tissue Recovery LLC at: **(336) 448-1910** or **info@birthtissuerecovery.com**



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