

# **Explanation of receiving Cell Donation and Regenerative Medicine**

Name of regenerative medicine:

Treatment of autoimmune diseases using autologous adipose (tissue)-derived mesenchymal stem cells

This information document is intended to help you understand the details of regenerative medicine donation correctly and to help you decide whether or not to donate cells and receive regenerative medicine based on your will. Please read this instruction document carefully, listen to the explanation of your physician, and decide whether or not to undergo cell donation or regenerative medicine after careful consideration. If you have any questions, please feel free to ask us any questions you may have.

## **1. Name of the regenerative medicine and notification to the Ministry of Health, Labour and Welfare**

The name of this therapy is “Treatment of autoimmune diseases using autologous adipose (tissue)-derived mesenchymal stem cells”. Based on the “Act on Safety Assurance of Regenerative Medicine”, a “Plan for Provision of Regenerative Medicine” has been submitted to the Minister of Health, Labour and Welfare.

## **2. Information regarding medical institutions that receive cell donations, medical institutions that provide regenerative medicine**

Name of medical institution: AB beauty & Cell Clinic

The administrator of the medical institution: MICHIKO FUKUDA, hospital director

Person in charge of regenerative medicine: SHIM JOONBO

Physician who collects cells: SHIM JOONBO

Physician providing regenerative medicine: SHIM JOONBO

## **3. Purpose and details of the use of the cells and regenerative medicine**

The cells to be collected this time will be used for the “treatment of autoimmune diseases using autologous adipose (tissue)-derived mesenchymal stem cells”. This treatment aims to improve the symptoms of autoimmune diseases by utilizing the ability of autologous adipose-derived mesenchymal stem cells to secrete immunosuppressive and anti-inflammatory factors. At first, the patient’s fat is extracted, and adipose-derived stem cells extracted from the fat are grown to the required number of cells by culture. Once the number of cells has grown to a sufficient number, they are administered intravenously (intravenous infusion). Since the patient’s blood is used to culture the cells, blood is also collected along with the fat collection.

## **4. Reasons for being selected as a cell donor**

Since this treatment uses cells collected from the person (you) who is to receive the regenerative medicine, you have been selected as a cell donor.

(Selection criteria)

You must be the person who will receive the regenerative medicine.

(Exclusion criteria)

We do not set our exclusion criteria as a cell donor.

The criteria for recipients of regenerative medicine, etc. are as follows.

**【Selection criteria】**

Persons who meet all of the following criteria shall be eligible for this treatment.

- Patients who have been diagnosed with the following autoimmune diseases, whose main symptoms have not improved with existing conservative therapies, and whose need for this regenerative medicine is considered to be high.

- (1) Atopic dermatitis
- (2) Rheumatoid arthritis
- (3) Psoriasis vulgaris

- Patients aged 20 to 80 years

\*For patients over 80 years of age, the physician administering this treatment will determine whether or not to provide treatment, taking into consideration the health and physical conditions of the person receiving the treatment.

**【Exclusion Criteria】**

The following persons are excluded from this treatment.

- Those who have experienced hypersensitivity or allergic symptoms to anesthetics used in fat harvesting or to substances used in the manufacturing process of specific cellular processed products.
- Those who have developed an infectious disease.

The physician who performs the treatment will make the final decision on whether or not to provide the treatment.

**5. Regarding cells used for regenerative medicine**

Adipose tissue is collected at our clinic, and stem cells are cultured at a facility affiliated with our clinic to increase the number of stem cells until they become the necessary cells, which are then administered intravenously.

## **6. Benefits (e.g., effects) and disadvantages (e.g., risks) of donating cells and receiving regenerative medicine.**

The following benefits and disadvantages are expected from the donation of cells and treatment.

The administration of adipose-derived stem cells is expected to improve the symptoms of autoimmune diseases by suppressing attacks on the self by the immune system and the resulting inflammation through the action of immunosuppressive factors and anti-inflammatory factors secreted from adipose-derived stem cells. The risks associated with this treatment include complications and side effects that may occur with fat harvesting and administration of the cells. In addition, although the causal relationship is unknown, there have been cases in which patients who received intravenous infusion of adipose-derived stem cells have died due to pulmonary embolism (a condition in which the blood vessels in the lungs become clogged).

<About Albumin Products >

Human serum albumin is added to the product to maintain cell activity and viability. This product is formulated from human blood, and at the time of collection of the raw material, a medical examination and tests related to infectious diseases are conducted. In addition, certain inactivation and removal processes are performed during the manufacturing process, and safety measures against infectious diseases are taken. However, since viruses such as human parvovirus B19 and abnormal prions that cause variant Creutzfeldt-Jakob disease cannot be eliminated, the possibility of their infection cannot be ruled out. Although the frequency is unknown, shock and anaphylaxis may occur as serious adverse reactions. Other side effects may include hypersensitivity (hypersensitivity to the drug) and anaphylaxis (anaphylaxis). Other possible side effects include hypersensitivity (fever, facial flushing, urticaria, etc.), chills, and back pain.

## **7. You may refuse to donate cells or undergo regenerative medicine**

You will not be forced to donate cells or receive this treatment. After receiving an explanation, if you decide that you should not receive cell donation or this treatment, you may refuse to donate cells or receive this treatment at any time.

## **8. Withdrawal of Consent**

You may withdraw your consent at any time, even if you have given your consent to donate cells or to receive this treatment.

## **9. There is no disadvantageous treatment due to refusal or withdrawal of consent**

You will not be disadvantaged in any way in your future medical care or treatment, even if you refuse to receive the cell donation or this treatment after receiving an explanation or withdraw your consent after having agreed to receive the cell donation or this treatment.

## **10. Protection of Personal Information**

Personal information obtained in the course of treatment will be properly managed and protected, and will not be disclosed outside the clinic. However, treatment results might be anonymized and used for presentation and reporting to related academic societies to improve the effectiveness of treatment, and for publication of the clinic's treatment results.

## **11. Storage and disposal of cells and other materials**

To investigate the cause of any disease suspected to be caused by this treatment, blood samples will be frozen and stored for 10 years, and a portion of cultured adipose-derived mesenchymal stem cells will be frozen and stored for 30 years. After the storage period, the adipose-derived stem cells will be disposed of as medical waste by contracting disposal to a contractor.

## **12. Attribution of Patent Rights, Copyrights, Other Property Rights, and Economic Benefits Related to Regenerative Medicine**

Any new patent rights, copyrights, other property rights, or economic benefits arising from regenerative medicine using cells donated by you will belong to our hospital.

## **13. Complaint and Inquiry System**

The clinic has established a contact for complaints and inquiries regarding this treatment method as follows. After receiving a complaint or inquiry at the contact counter, it will be reported to the treating physician and the administrator (hospital director) for handling.

Contact (department in charge: Administration Office)  
Phone number: +81 90-9109-0114

## **14. Costs**

When providing treatment, the patient will be asked to pay 2,200,000 yen (including tax)/treatment as our prescribed fee, as this treatment is not covered by public insurance.

\*The treatment fee may vary depending on the patient's symptoms and other circumstances.

Please note that if a patient withdraws consent after the collection or processing of cells, or if any costs have been incurred up to the time of withdrawal of consent, the patient will be responsible for any costs incurred.

## **15. Availability of other treatment methods and comparison with this treatment method**

One treatment for autoimmune diseases is to suppress the autoimmune response by suppressing the immune system through the administration of medications. However, many of the medications used to control autoimmune reactions also reduce the body's ability to fight disease, especially infection. The long-term use of medications that suppress the immune system (immunosuppressive drugs), such as azathioprine, chlorambucil, cyclophosphamide, cyclosporine, mycophenolic acid, and methotrexate, can be expected to reduce the symptoms of autoimmune diseases. However, these medications not only suppress the autoimmune response, they also suppress the body's ability to defend itself against foreign substances, including infection-causing microorganisms and cancer cells, thus increasing the risk of developing certain types of infections and cancers. In addition, because of the administration of medications, there is also the risk of side effects. The benefits of this treatment are that the patient's adipose-derived stem cells are administered, so there is no risk of side effects, and there is less risk of infection or cancer development due to a weakened immune system compared to the administration of medications.

## **16. Compensation for health damage**

In the event of any health problems that may be caused by the donation of cells or this treatment, please contact us immediately so that we can take the necessary measures to the best of our ability.

## **17. Regarding information and matters to be examined by the Accredited Committee for Regenerative Medicine, which examines regenerative medicine**

According to the “Act on Securing Safety of Regenerative Medicine,” regenerative medicine provision plans must be reviewed by a “Certified Regenerative Medicine Committee” before submission to the Minister of Health, Labor, and Welfare. Our clinic has undergone the following review of the regenerative medicine provision plan for this treatment.

The Certified Committee for Regenerative Medicine, that conducted the review:  
Vivian Specific Certified Committee for Regenerative Medicine

Contact for complaints and inquiries: 080-2740-2323.

Matters examined: A plan for the provision of regenerative medicine, and a set of attached materials are submitted for review in light of the “Standards for the Provision of Regenerative Medicine”, established by the “Act on Safety Assurance of Regenerative Medicine”.

## **18. Other important notes**

- After receiving this treatment, you will be asked to return to the clinic once every 30 days until 6 months after the date of the treatment for periodic follow-up visits to verify the occurrence of health problems and the effectiveness of the treatment. In addition, we may ask you to visit the clinic at other times if necessary.
- The human genome and genetic analysis will not be performed in the course of this treatment.
- We will not use the cells collected during the treatment or the specific cellular products manufactured during the treatment for any other treatment or research in the future.

## Consent Form

AB beauty & Cell Clinic

To: Dr. MICHIKO FUKUDA, hospital director

I have received the following explanation regarding the donation of cells for regenerative medicine, etc. (name: “Treatment of autoimmune diseases using autologous fat (tissue)-derived mesenchymal stem cells”).

- Name of regenerative medicine and notification to the Ministry of Health, Labour, and Welfare.
- Information about the medical institution to which the cells will be donated.
- Usage of the cells.
- Reason for being selected as a cell donor.
- Benefits (e.g., effects) and disadvantages (e.g., risks) of cell donation.
- Rights to refuse the cell donation.
- Withdrawal of consent.
- Rejection of cell donation or withdrawal of consent will not cause any disadvantageous treatment.
- Protection of Personal Information.
- Regarding storage and disposal of cells and other materials.
- Regarding patent rights, copyrights, other property rights, and economic benefits related to regenerative medicine.
- Complaint and inquiry system.
- Regarding the cost.
- About compensation for damage to health.
- Information and other matters to be examined by the Accredited Committee for Regenerative Medicine, which examines regenerative medicine.
- Other important notes.

I have received the following explanation regarding the provision of regenerative medicine (name: “Treatment of autoimmune diseases using autologous fat (tissue)-derived mesenchymal stem cells”).

- Name of regenerative medicine and notification to the Ministry of Health, Labour, and Welfare.
- Information on the medical institution providing regenerative medicine.
- Purpose and details of the regenerative medicine.
- Cells to be used for regenerative medicine.
- Benefits (e.g., effects) and disadvantages (e.g., risks) of receiving regenerative medicine.
- The right to refuse to receive regenerative medicine.
- Withdrawal of consent.
- The fact that no one will be treated disadvantageously by refusing to receive regenerative medical treatment, or withdrawing consent.
- Protection of Personal Information.
- Storage and disposal of cells and other materials.
- Complaint and inquiry system.
- Regarding the cost of the treatment.
- Availability of other treatment methods and comparison with this treatment method.
- About compensation for damage to health.
- Information and matters to be reviewed by the Accredited Committee for Regenerative Medicine, which examines regenerative medicine.
- Other important notes.

I have explained the above information to the patient.

Date of explanation \_\_\_\_\_

The doctor in charge of the explanation \_\_\_\_\_

I fully understand the above explanation and agree to receive the donation of cells and regenerative medicine. I confirm that I can withdraw this consent at any time before the start of cell processing or treatment.

Date of Consent \_\_\_\_\_

Patient's Signature \_\_\_\_\_

Signature of the legal representative \_\_\_\_\_

(Relationship with the patient \_\_\_\_\_)

## Consent Withdrawal Form

AB beauty & Cell Clinic

To: Dr. MICHIKO FUKUDA, hospital director

I hereby withdraw my consent to the donation of cells for regenerative medicine (treatment of autoimmune diseases using autologous adipose (tissue)-derived mesenchymal stem cells).

I have no objection to bearing the costs of treatment and other expenses incurred before I withdraw my consent.

Date of withdrawal \_\_\_\_\_

Patient's Signature \_\_\_\_\_

Signature of the legal representative \_\_\_\_\_

(Relationship with the patient \_\_\_\_\_)



## Consent Withdrawal Form

AB beauty & Cell Clinic

To: Dr. MICHIKO FUKUDA, hospital director

I hereby withdraw my consent to receive regenerative medicine, etc. (name: “Treatment of autoimmune diseases using autologous adipose (tissue)-derived mesenchymal stem cells”).

I have no objection to bearing the cost of treatment and other expenses incurred before I withdraw my consent.

Date of withdrawal \_\_\_\_\_

Patient's Signature \_\_\_\_\_

Signature of the legal representative \_\_\_\_\_

(Relationship with the patient \_\_\_\_\_)