

# ADSCs CRYOPRESERVATION AGREEMENT

BIOSCIENCE INSTITUTE S.p.A., based in via Rovereta, 42 – 47891 Falciano -Republic di San Marino in the person of Giuseppe Mucci, as Chairman of the Board of Directors. – Codice Operatore Economico 20021 Pubblico Registro delle Società numero: 3794

#### 1. Premises

- 1.1 With this document (hereafter referred to as AGREEMENT), the undersigned (hereafter referred to as USER) gives Bioscience Institute the task to treat, analyse and store by freezing stem cells derived from adipose tissue (Adipose Derived Stem Cells, hereafter referred to as ADSCs) extracted from a lipoaspirate SAMPLE (hereinafter referred to as SAMPLE) obtained from medical staff external to BIOSCIENCE INSTITUTE. This AGREEMENT is therefore binding upon the signature of the same. By signing this AGREEMENT, the USER agrees to have the SAMPLE treated, analysed and stored at the BIOSCIENCE INSTITUTE laboratory for autologous use and declares his acceptance to the following:
- **1.2** The USER is aware and informed that it is in no way possible to predict and guarantee the performance of the extraction, expansion, freezing and conservation processes of any biological material, and therefore also of the ADSCs.
- 1.3 The premises are a substantial part of this AGREEMENT.

#### 2. Object, duration and effectiveness of the AGREEMENT

- **2.1** The object of the present AGREEMENT is: the extraction, expansion, analysis and cryopreservation of autologous ADSCs obtained from an adipose tissue collection sent to the LABORATORY located in Falciano, via Rovereta 42 Republic of San Marino, exclusive property of BIOSCIENCE INSTITUTE.
- **2.2** This AGREEMENT has a duration of 3 (three) years, except in case of termination of the cryopreserved biological material. In this case, the term of the AGREEMENT coincides with the release of the last aliquot of biological material.
- **2.3** The AGREEMENT begins to produce effects starting from the date of subscription.

### 3. SAMPLE collection

- **3.1** The collection procedure must be agreed exclusively between the USER and his medical staff; the SAMPLE must be at least 10 (ten) ml. In case with a lower volume collection, BIOSCIENCE INSTITUTE will not be responsible for the yield of the processes, object of the present AGREEMENT, and will eliminate the sample.
- **3.2** In any case, BIOSCIENCE INSTITUTE will not be responsible for the action of the medical staff chosen by the USER for the collection of the SAMPLE.

## 4. Obligation before the transport

**4.1** Once the SAMPLE has been collected, it is USER's obligation to ensure that all the tubes containing it are correctly labelled with proper identification data. BIOSCIENCE INSTITUTE is exonerated from responsibility for errors in preparation and transport of the SAMPLE.

# 5. Essential conditions for treatment and storage

**5.1** In order to make effective this AGREEMENT, in the thirty (30) days prior to collection, it is essential that the following TESTS are performed on the blood of the USER: anti-HIV 1-2, HBsAg, Total anti-HBc (IgG and IgM), anti HCV, TPHA, anti HTLV 1-2, anti-CMV (IgG and IgM). All tests must be negative; the only exception is represented by the anti-CMV IgG analysis which can be positive, if the corresponding anti-CMV IgM is negative. If the anti-HBc IgG assay is positive and the corresponding anti-HBc IgM is negative, further investigations will be required.

Any other investigations could be requested on the basis of the USER's clinical history.

Moreover, it is mandatory to send a copy of the results of the TESTS (bearing the collection date, USER's name and the physician's original signature) to BIOSCIENCE INSTITUTE before submitting to fat collection. In the event that these results do not arrive according to the aforementioned timing, BIOSCIENCE INSTITUTE will keep the SAMPLE up to 72 hours after collection; after this period the SAMPLE will be deleted.

## Transport

**6.1** The SAMPLE must arrive at BIOSCIENCE INSTITUTE within 72 hours of collection. Collection must be avoided close to the

holidays and must, in any case, be previously agreed with BIOSCIENCE INSTITUTE, which will activate the procedure for the transport of the SAMPLE by courier.

**6.2** In no case BIOSCIENCE INSTITUTE is responsible for any damage, loss, delayed delivery or other event connected to the transport of the SAMPLE, which is the responsibility of the courier.

#### 7. Services

- **7.1** The SAMPLE, once arrived at BIOSCIENCE INSTITUTE, will be treated according to internal Standard Operating Procedure (SOPs).
- **7.2** The USER expressly accepts that BIOSCIENCE INSTITUTE performs on the SAMPLE all the tests required for the treatment and storage procedures.
- **7.3** BIOSCIENCE INSTITUTE will store the SAMPLE in appropriate cryobiological containers approved for the specific use. The USER expressly authorizes BIOSCIENCE INSTITUTE to transfer the SAMPLE, if necessary, to another laboratory or any other appropriate place, provided that he is promptly informed, ensuring a quality level of treatment and storage at least equal to that guaranteed until that moment.

# 8. Services description

**8.1** BIOSCIENCE INSTITUTE performs the procedures of extraction, culture and cryopreservation of ADSCs. The eventual release of the ADSCs occurs in case of request by the USER or the doctor. USER remains the only owner of ADSCs.

#### 9. Fee

- **9.1** The quotation varies according to the type of service requested and, in any case, includes the first 3 (three) years of cryopreservation of biological material.
- **9.2** At the end of the first 3 (three) years, the period of cryopreservation of biological material may be extended by a further 3 (three) years, upon request and payment according to the price list. This extension will be subjected to the same conditions as the present AGREEMENT.
- **9.3** Payment must be made before the collection of the adipose tissue sample, as described at the end of the present AGREEMENT.

## 10. Rights on the SAMPLE

- **10.1** All the rights on the SAMPLE are conferred to the USER.
- 10.2 In the event of at least two consecutive sterility tests being positive, the SAMPLE must be eliminated in all its parts, to avoid the risk of environmental contamination. In this circumstance BIOSCIENCE INSTITUTE has the right to eliminate the sample without the need for authorizations from the USER. BIOSCIENCE INSTITUTE, within 20 (twenty) working days from the date of elimination, makes the related communication to the USER.
- 10.3 In case of termination of the AGREEMENT as foreseen in the following point 15, BIOSCIENCE INSTITUTE, within 20 (twenty) working days from the resolution date, will provide the proper communication to the USER; from that moment all the rights or claims on the SAMPLE will be deemed expressly waived and BIOSCIENCE INSTITUTE will be authorized to delete it.
- **10.4** If the USER requests to eliminate the SAMPLE, BIOSCIENCE INSTITUTE will send a SAMPLE elimination authorization form. The form must be duly completed and signed by the USER and returned in original by registered letter with return receipt to BIOSCIENCE INSTITUTE. Upon receipt of the form all rights or claims to the SAMPLE will be deemed expressly waived and BIOSCIENCE INSTITUTE will be authorized to delete it.

## 11. USER's guarantee

11.1 The USER expressly declares to have evaluated with a competent doctor every aspect related to the collection, transport, analysis, freezing and cryopreservation of the SAMPLE; to have carefully examined the present AGREEMENT and to fully accept without reserve all the provisions inserted therein; to be informed that the collection, transport, analysis, freezing, storage

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and any possible use of ADSCs derive from expression of the conscious declaration of USER's will.

## 12. Limitations of liability

- **12.1** BIOSCIENCE INSTITUTE will not be responsible for the work of the medical staff charged by the USER or by BIOSCIENCE INSTITUTE for the collection of the SAMPLE nor for transport up to BIOSCIENCE INSTITUTE.
- **12.2** BIOSCIENCE INSTITUTE will not be required to perform any medical services, medical advice or any other function other than those described in this AGREEMENT.
- **12.3** BIOSCIENCE INSTITUTE does not guarantee that the SAMPLE collected will be qualitatively and quantitatively sufficient to perform the processes of cryopreservation or for future use for any purpose.
- **12.4** BIOSCIENCE INSTITUTE is not accountable for any interruption or alteration of the cryopreservation process due to exceptional factors or circumstances beyond its control. BIOSCIENCE INSTITUTE activates without delay all the procedures for the maintenance of the characteristics of the SAMPLE, according to the GMP standard.
- **12.5** USER unreservedly accepts exclusion of liability contained in points 12.1 to 12.5.

### 13. Damages

**13.1** BIOSCIENCE INSTITUTE will respond only in case of intentional fault and serious misconduct. In this case the compensable damage is limited exclusively to the total amount paid under this AGREEMENT. Any further damages of any kind will not be reimbursed

### 14. Withdrawal

**14.1** The USER may withdraw from this AGREEMENT by registered letter with acknowledgment of receipt or FAX to be sent to BIOSCIENCE INSTITUTE within the terms provided by the AGREEMENT.

#### 15. Termination of the AGREEMENT

 $15.1\,\mathrm{The}$  AGREEMENT can be resolved by mutual agreement of the PARTIES.

**15.2** BIOSCIENCE INSTITUTE may resolute this AGREEMENT in case of total or partial non-payment of the price; in any case the termination will be effective after 15 (fifteen) working days from the sending to the USER, by registered letter with return receipt, of the warning to abide.

# 16. Legislation, competence

**16.1** This AGREEMENT is subject only to the legislation in force in the Republic of San Marino. The competent judicial authority, in the event of a dispute, is exclusively the one of the Republic of San Marino.

The parties expressly waive the right to propose exceptions with respect to the jurisdiction as identified above and undertake to execute judgments delivered by the Judicial Authority of San Marino, concerning the present AGREEMENT.

#### 17. Arrangements

17.1 The entirety of the arrangements between BIOSCIENCE INSTITUTE and the USER are transfused into the present AGREEMENT. Any other previous contract is replaced by this AGREEMENT. Any future agreements must be written and signed by the parties.

## 18. Retention of AGREEMENT

**18.1** If any provision of this AGREEMENT, void or unenforceable shall be amended in order to make it enforceable. The remaining provisions shall remain in full force and effect.

#### 19. Communication

**19.1** Communications concerning this AGREEMENT must be made in writing form, according to the procedures from time to time specified.

# 20. Confidentiality

**20.1** The Parties note that all information concerning this AGREEMENT are confidential. BIOSCIENCE INSTITUTE will adopt all necessary measures in order to keep such information confidential, except in cases where the legislation provides otherwise.

### 21. Domiciliary and relevant information

**21.1** For the purposes of this AGREEMENT, the USER declares the domicile at the address of residence.

USER data			
Surname	Name	Born in	Date of birth
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Nationality	Fiscal Code	Home address	N.
City	ZIP code	Country	
Mobile Phone	Phone	E-mail	
Medical facility where the SAMPLE collection is performed			
Medical facility	Address	City	Phone
Bank account details for payment with bank transfer			
Advance payment by bank transfer is required BENEFICIARY: BIOSCIENCE INSTITUTE spa CAUSAL OF THE TRANSFER: DATE AND PROFORMA INVOICE NUMBER FOR THE BALANCE OF SERVICES  BAC Istituto Bancario Sammarinese S.p.A IBAN SM94L0303409812000120102394 - BIC BASMSMSMXXX			
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Date	USER's signature	BIOSCIENCE INSTITUTE S.p.,	Α.
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