DOKU BIOTECHNOLOGY Stem Cell, Biobank and Tissue Engineering Centre shall prepare the requested product under national and international standards or store by processing upon the **Cellular Product Order Form (SUY-03-01), Cellular Product Manufacturing Agreement Form (SUY-03-02)** mutually signed with you and upon signing this approval form as the result of the request received after your (donor/recipient) and your doctor (receiver and administrator of the raw product).

It should be acknowledged that stem cell and other cellular applications are completely experimental applications, the benefit to be achieved as the result of the application may vary between individuals, long term unknown side effects may be encountered other than known and below defined side effects affiliated with this process. No percentage success expression, certainty, promise, result warranty is given regarding the benefit or the amount of the benefit and upon signing this form, it is assumed that you understand this disclosure, also you are informed by the doctor, and you accepted the cellular product administration with your own will by making the required research under your responsibility.

Stages of the Process

1. During the cellular product manufacturing stage; your own serum, plasma or special consumables or solutions complying with the human tissue and cell product manufacturing expressed in current IIU (GMP) guide published by the Ministry of Health, regulations or statements. Your cells will be subjected to freezing process in the long term storage – keeping – banking process, and will be kept at a temperature under -130°C during the storage period indicated by the Ministry of Health. (In case a banking service is requested, forms to be shared with you should be filled end signed).

2. Cellular product will be prepared in the final product form by subjecting to certain processes on the date of request to be administered to you. Cellular final product will be delivered to your doctor or the authorized person or authority/organization assigned by your doctor with the certificate (Related Cellular Product Emission Certificate) indicating that it complies with required quality norms in terms of cell count and vitality, bacterial endotoxin, sterility, quick sterility, purity-identity, activity and mycoplasma (additionally the genetic stability and senescence for mesenchymal stem cells and cells with allogenic use). Concerned clinic personnel and the administrator doctor are responsible for storing the product under suitable conditions and sustaining its quality after the delivery. Our centre is not responsible for suitability of storage conditions of cellular products after deliver until administration to the recipient. Therefore, it is critical to follow rules of storage and preparation of the product for administration notified by our centre and additionally indicated in the concerned cellular product emission certificate or TOP-10 Cellular Final Product Instructions of Use and the doctor is responsible for different storage, preparation and administration forms.

3. In accordance with the legal regulation, your post-administration status will be monitored through your doctor for two years in total as regular periods.

4. As in every injection application, it should be known that complications such as allergic reactions, redness, headache, quiescence, febricula, hypo/hyper tension and administration related infection may occur rarely during the cellular product injection. Experimental status of the application makes it possible to see unknown, undefined side effects, also the administered product may not meet requirements partially or completely. In this regard, it is assumed that you are informed by the doctor receiving the raw product and you accepted the cellular product administration by making required research under your responsibility.

5. It should be known that you permit BIYOTEKNOLOJI LTD. STI. forthe residual tissues/cells from the interim and final product acquired upon processing the raw product taken from you other than your request to be used for research/development, validation, clinic studies and therefore you will not have any tangible or intangible expectations for this reason. However, your personal information will be kept confidential in the laboratory and not disclosed to 3rd persons under any names. Acquired data may be used in scientific studies without using your name upon approval of your doctor.

6. After the raw product (tissue/cell) to be used in preparation of the requested product is received and approved by the laboratory, the cellular product to be produced or produced will be delivered to your doctor to be administered to you on the mutually agreed date (doctor-laboratory). It should be known that you are obliged to make your administration on that date, otherwise the material planned to be administered to you must be destroyed due to containing live cells and accordingly, your administration right will be lost. Your doctor is responsible for acquiring the raw product and administering the final cellular product; and it is assumed that short, medium and long term possible side effects and complications after receiving and administering the raw product are completely expressed to you by your doctor and you understood and accepted them. Received raw product will be delivered to DOKU BIOTECHNOLOGY Stem Cell, Biobank and Tissue Engineering Centre within 48 hours at latest and in case preliminary quality control test results are suitable and serology test results are negative, it shall be subjected to required processes depending on your requests and to be stored under short or long term freezing based on your demand indicated in the Cellular Product Order Form or when required. One or more of below given processes may be administered to the raw product received from you.

(a) Enzymatic or mechanic fractionation of the tissue,

(b) Selecting / isolating requested cells,

(c) Reproducing in cell culture vessels,

(d) When required, reproducing on a matrix or combining with the matrix/material,

(e) Stages of freezing your cells when required or depending on your requests,

(f) If required by the laboratory, storing or producing part of the cells to be acquired out of your request to be used in research/development, validation, clinical studies,

7. Which approach do you accept regarding future of your residual products acquired during the entire production and storage processes?

a) I want my residual products to be sent to me; I will pay additionally 100 Euro service fee to DOKU BIOTECHNOLOGY against these products. (If no data is entered below, it will be accepted that you do not want them to be sent)

…….

List of Cellular Products Produced by the Doku Biotechnology Stem Cell, Biobank and Tissue Engineering Centre:

1. Mesenchymal Stem Cell from Bone Marrow (Kİ-MKH)
2. Mononuclear Cell from Bone Marrow (Kİ-MNH)
3. Mesenchymal Stem Cell (GK-MKH)from Umbilical Cord (Wharton Gel)
4. Mesenchymal Stem Cell (GK-MKH) from Fat Tissue
5. Stromal Vascular Fraction (SVF) from Fat Tissue
6. Mononuclear Cell from Cord Blood(KK-MNH)
7. Mesenchymal Stem Cell from Dental Pulp (DP-MKH)
8. Fibroblast from Dermal or Connective Tissue(FIB)
9. Keratinocyte from Dermal Tissue(KER)
10. Dermal Papilla from Hair Follicles (DP)
11. Fibroblast from Foreskin(SD-FIB)
12. Collagen Membrane Combined with Chondrocyte from Cartilage Tissue(KON)

RECIPIENT CONSENT FORM

I completely read explanations made by DOKU BIOTECHNOLOGY Stem Cell, Biobank and Tissue Engineering Centre through agreements and forms regarding the product or products mentioned in the above list and specifically indicated in the Cellular Product Order Form, I learnt meanings of foreign words by asking to my doctor and/or by making my own researches. I asked my questions to my doctor, shared my concerns with him and I decided the administration with my own will by knowing the possibility of not having any benefit from this treatment. I hereby accept and declare that I have consent for DOKU BIOTECHNOLOGY Stem Cell, Biobank and Tissue Engineering Centre to prepare autologous or allogenic cellular product and my doctor to realize the administration with all possible or unexpected side effect, risk and complications.

Donor/Recipient(or tutor) Name Surname :

Level of Relation :

Date/Hour :

Signature :

DOCTOR CONSENT TEXT

I hereby authorize DOKU BIOTECHNOLOGY Stem Cell, Biobank and Tissue Engineering Centre to prepare ……. **coded product or products** required for the recipient / donor indicated by me in the Cellular Product Order Form FOR experimental application purposes. I have adequate level of knowledge regarding all benefits or possible or unexpected risks for this treatment and I am making this choice for the Recipient knowingly. I accept that I will share all developments for this product with DOKU BIOTECHNOLOGY Stem Cell, Biobank and Tissue Engineering Centre if required. I accept not to share with third persons without written permission of DOKU BIOTECHNOLOGY Stem Cell, Biobank and Tissue Engineering Centre signed by the authorized person. I know that I have to use the name of DOKU BIOTECHNOLOGY Stem Cell, Biobank and Tissue Engineering Centre as the centre producing the product in scientific publications.

Doctor Name/

Surname: Specialty:

Diploma noor Stamp:

Date/Hour:

Signature: