UNIVERSITÄTS KLINIKUM jena | Placenta-Labor

Klinik für Geburtsmedizin
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Treatment contract for examination of uterine cells

Initial analysis

To be filled in by patient

I have been informed in detail about the analysis of uterine natural killer cells (uNK), plasma cells and the detection of defined bacterial species in a biopsy of the endometrium. I agree that the analysis will be carried out by the Placenta Lab of the Clinic for Obstetrics at the Jena University Hospital and that the costs will be charged to me as a self-payer service. I have been informed that patient confidentiality and data protection as required by law will be respected.

First name: _____

Last name: _____

Date of birth: |__|__|.|__|__|.|__|__|__|__|

Address: _____
Street, House number

_____
Postcode, City

_____
E-mail address

Patient sticker

I commission the Placenta Lab on the basis of the German GOÄ ("*Gebührenordnung für Ärzte*") to perform the following analysis on private invoice. A detailed list of the services is available on our website www.uniklinikum-jena.de/geburtsmedizin/EndometriumDiagnostik. ***If I, the patient, do not receive any or no reimbursement of the invoiced fees from my health insurance, I am obliged to bear these costs myself.***

Initial analysis:

☐	Combined analysis of the number of uterine natural killer cells and plasma cells	**226,20 €**
☐	Analysis of the number of uterine natural killer cells (CD56+)	**128,28 €**
☐	Analysis of the number of uterine plasma cells (CD138+)	**128,28 €**

Additional offers for individual therapy recommendation

☐ Cytotoxic activity of uterine NK cells (CD16+) * **additional 48,96 €**

* additional analysis of highly cytotoxic CD16+ cells will be carried out only upon analysis of CD56+ uNK cells with levels of 100-400 uNK cells/mm²

☐ Endometrial germ analysis (micro/molecular biological analysis) **additional 99,09 €**

* additional micro/molecular biological analysis for analysis of CD138+ plasma cells
** submission of an additional tissue sample in culture medium necessary

Additional costs of 5,95 € may incur for postage and shipping material.

Right to object: I have the right, at any time to file an objection to specific decisions or measures concerning the processing or use of personal data relating to me (Article 21 DSGVO, §36 BDSG-new). Such processing or use of my personal data will be subsequently and indefinitely discontinued. The objection is effective upon receipt in the Placenta Lab.

I expressly declare that I have understood the meaning and content of this consent.

_____ _____
Place, Date of Signature Signature of patient

Patient information sheet

To be completed by the attending physician

Clinic/ Physician stamp

☐ Natural cycle

☐ Artificial cycle Preparation: _____

Day of cycle: |__|__|

Cycle length of last cycle: |__|__|

Number of days after ovulation: |__|__|

First day of last period: |__|__|.|__|__|.|__|__|__|__|

Number of days since last unprotected intercourse |__|__|__|

☐ **Patient with recurrent miscarriages (RSA)**

☐ **Patient with implantation failure (RIF)**

Gravida: |__|__|

Para: |__|__|

Early miscarriages (< 12. SSW): |__|__|

Late miscarriages (> 12. SSW): |__|__|

Number of previous IVF/ICSI cycles: |__|__|

Number of embryo transfers: |__|__|

Total number of transferred embryos: |__|__|

Comments/ identified risk factors: _____

Relevant (pre-exisiting) diseases: _____

Medication intolerances: _____

Existing or past therapies:

Antibiotic therapy:

_____
Preparation Dose Period

Immunosuppressive therapy:

_____
Preparation Dose Period

Other therapy, e.g. probiotics:

_____
Preparation Dose Period

_____ _____

Place, Date of Signature Signature of attending physician

Patient sticker or alternatively name and address in block capitals

Patient information

on the donation, storage and use of residual samples and transmission of clinical treatment data

Dear patient,

You have ordered the immunological analysis of the endometrium from us. We would like to thank you for your trust. After completion of the examinations, the remaining tissue of these samples are normally destroyed. However, these sample remnants can be of **great value** for research in relation to **fertility treatments**:

If the samples are further investigated, e.g. with new experimental methods, knowledge could be gained for both basic research and the development of new diagnostic and therapeutic procedures. In order to use these sample remnants for research, we would hereby like to ask you to give your consent to the storage of these remnant materials in the Placenta Lab and to their use for research. This is a simple way for you to support medical research without any additional burden. **No additional samples will be taken from you!**

The samples will be stored securely until used for research and will only be used within the UKJ if approved in advance by the UKJ Ethics Committee.

So that a reference to your person (personal reference) is no longer possible, the samples are only stored anonymised or pseudonymised. Anonymised means that the samples and disease data can no longer be assigned to your person. Pseudonymised means that your personal data is replaced by a letter-number code.

Consent

I make no personal or financial claims in connection with the use of my samples. I have been informed that I have the right to revoke the use of the residual samples at any time, even without giving reasons. In this case, the residual samples will be destroyed if they have not been anonymised. I waive the right to feedback of results collected with the residual samples provided. A copy of my signed declaration of consent has been handed over to me.

I have received, read and understood this patient information. I have been informed in detail about the aim, the benefits and my rights, if samples are provided and the voluntary nature of participation. I had the opportunity to ask questions, which were answered satisfactorily and completely.

I consent to the use for scientific research of any material that was necessarily taken from me for diagnosis and/or therapy and that is no longer required for further diagnostic or therapeutic measures (hereinafter referred to as residual samples). For this purpose, I transfer these residual samples to the University Hospital Jena.

☐ No, I do not agree to my residual samples being used for research.

Yes, I agree to the following points (please tick "yes" if you agree):

☐ Yes, I agree that further clinical data related to my treatment may be transmitted to the Placenta Lab.

☐ Yes, I agree to further treatment-related contact by the Placenta Lab.

☐ Yes, I agree that my residual samples **without personal reference** can be used for research.purposes **within the Jena University Hospital.**

Date **Patient´s signature**

Information for patients according to the European General Data Protection Regulation (GDPR)

Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data, on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation).

You are hereby informed of your rights as set out in the GDPR (Article 12 et seq. GDPR):

Legal basis: In the case of clinical trials, the legal basis for the processing of your personal data is your voluntary written consent in accordance with the GDPR and the Declaration of Helsinki (Declaration of the World Medical Association on the Ethical Principles for Medical Research Involving Human Subjects) and the Guideline for Good Clinical Practice. In the case of drug studies, the German Medicines Act is also the legal basis. The revised Federal Data Protection Act (BDSG-neu) comes into force in Germany at the same time as the GDPR.

Person responsible for data processing: The project manager named in the clarification in each case is responsible for data processing within the scope of research projects (hereinafter referred to as clinical studies). In matters of data protection, this person reports to the person in charge of data protection at the UKJ.

Right to information: You have the right to information about the personal data concerning you that is collected, processed or, if applicable, transferred to third parties in the context of the clinical trial (handing over a copy) (Article 15 DSGVO, §§34 and 57 BDSG-neu).

Right to rectification: You have the right to have inaccurate personal data concerning you rectified (Articles 16 and 19 DSGVO, Section 58 BDSG-neu).

Right to erasure: You have the right to erasure of personal data concerning you, e.g. if this data is no longer necessary for the purpose for which it was collected (Articles 17 and 19 DSGVO, §§ 35 and 58 BDSG-neu). However, you must be aware that the collected data may not be completely deleted or even allowed to be deleted due to other applicable regulations (ICH- GCP guideline).

Right to restriction of processing: Under certain conditions, you have the right to request the restriction of the processing of personal data, i.e. the data may only be stored, not processed. You must request this. To do so, please contact the responsible project manager (named in the declaration of consent) or the UKJ data protection officer (Articles 18 and 19 DSGVO, Section 58 BDSG-neu).

Right to data portability: You have the right to obtain the personal data relating to you that you have provided to the Clinical Study Manager. This allows you to request that this data be transferred either to you or, where technically possible, to another body designated by you (Article 20 GDPR).

Right of objection: You have the right to object at any time to specific decisions or measures concerning the processing of personal data relating to you (Art. 21 DSGVO, § 36 BDSG-neu). Such processing will then no longer take place.

Consent to the processing of personal data and right to withdraw this consent: The processing of your personal data is only lawful with your consent (Article 6 DSGVO, Section 51 BDSG- new). You have the right to revoke your consent to the processing of personal data at any time. However, the data collected up to this point may be processed by the bodies named in the patient information and consent form for the clinical trial (Article 7, Paragraph 3 DSGVO, Section 51 Paragraph 3 BDSG-neu).

If you would like to make use of one of these rights, please contact the UKJ's data protection officer. You also have the **right to lodge a complaint with a supervisory authority if** you believe that the processing of personal data concerning you violates the GDPR:

Data protection: Contact details of the data protection officer at the UKJ
Bachstraße 18, 07743 Jena
Phone: 03641 9 325624/ Fax: 03641 9 399925
E-mail: datenschutzbeauftragter@med.uni-jena.de