Informed consent for an endometrial biopsy and Endometrial Receptivity Array (ERA) diagnosis

DATA
Patient’s name: ____________________________________________________________
Medical history no.: _______________________________________________________
Gynaecologist’s name: ______________________________________________________

METHODOLOGY: DESCRIPTION AND PURPOSE OF THE ANALYSIS
ERA (Endometrial Receptivity Array) is a molecular tool that tells us if the endometrium (the mucous membrane lining the womb) presents a receptivity profile at around day 21 of the menstrual cycle, the time at which the endometrium is ready for embryo implantation. This molecular diagnosis method is based on measuring the gene expression profile of endometrial tissue.

Consequently, ERA helps determine if the endometrium presents the ideal conditions for the implantation of embryos by allowing the embryonic transfer to take place when the ideal time arrives, thus increasing the possibilities of successful in vitro fertilisation treatment.

PROCEDURE
To carry out this analysis, a biopsy of the endometrium needs to be done, which will have to be taken at approximately day 21 after your menstrual cycle began, or when your gynaecologist suggests the biopsy should be done. An endometrial biopsy consists in introducing an extremely thin cannula through your vagina so that it reaches the womb, where a small cylinder of endometrial tissue is absorbed. There is no less invasive technique available to obtain a sufficient amount of endometrial material, thus you will notice some discomfort caused by the procedure, and you may notice slight bleeding after the biopsy. However, this is the usual process with no added risks. There is a risk (<5%) that the biopsy procedure will fail to obtain a sufficient quantity and / or quality of tissue to be able to make a diagnosis. In this case, a new biopsy will be required.

In approximately 5% of cases diagnosed as Non Receptive the probability obtained is <0.5. Unfortunately, in these cases we are currently unable to offer a therapeutic solution based on our current knowledge.

After a diagnosis has been made, the biopsy sample shall be conserved on IGENOMIX’ premises for a 2-year period. Should more analyses need to be done to improve the endometrial receptivity diagnosis, you will be requested an informed consent. The sample shall be destroyed after this time.

CONFIDENTIALITY
Your identity and all your personal details shall be kept confidentially, unless the law states otherwise. The Health Authorities shall have access to them to review your medical records. As part of their occupational duties, the personnel with access to your personal details shall be subject to permanent professional secrecy.

Any personal details included in this document shall be included in a confidential automated file, which is duly registered in the Spanish Data Protection Agency in accordance with the specific terms set out in Law 15/1999, whose ownership corresponds to IGENOMIX, S.L. for the purpose of managing the above-described diagnosis study. At all times, the patient has the right to access, rectify and cancel such data, as acknowledged by the cited legislation on personal data protection, by writing to: IGENOMIX, S.L., C/Catedrático Agustín Escardino nº 9 Parc Científic, Edificio 3, Laboratorio 2.04, 46980 Paterna, Valencia, Spain.

HAVING READ AND UNDERSTOOD THE INFORMATION ON THE PREVIOUS PAGE, I HAVE BEEN INFORMED ABOUT:
The indication, procedure, chances of success, risks and complications of the proposed treatment, and the cost of this test;
The availability of the health personnel to extend any aspect of this information that may not have been made clear;
I have understood the explanations I have been provided with, which have been written clearly and simply, and the doctor who has seen us has allowed me to make all the observations I have wanted to and has resolved any doubts I have had.
I state that I am satisfied with the information received. I freely give my consent to undergo an endometrial biopsy in the ________________ assisted reproduction centre/clinic, and for the endometrial tissue sample to be sent to the premises of IGENOMIX, S.L. for a diagnosis to be made.
Likewise, I accept that the ERA (Endometrial Receptivity Array) results will be made known to my gynaecologist so that I can be suitably advised about my IVF treatment in accordance with these results.

In ________________, on ____ of ___________ in ___________
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Gynaecologist signature
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PROCEDURE
To carry out this analysis, a biopsy of the endometrium needs to be done, which will have to be taken at approximately day 21 after your menstrual cycle began, or when your gynaecologist suggests the biopsy should be done. An endometrial biopsy consists in introducing an extremely thin cannula through your vagina so that it reaches the womb, where a small cylinder of endometrial tissue is absorbed. There is no less invasive technique available to obtain a sufficient amount of endometrial material, thus you will notice some discomfort caused by the procedure, and you may notice slight bleeding after the biopsy. However, this is the usual process with no added risks. There is a risk (<5%) that the biopsy procedure will fail to obtain a sufficient quantity and / or quality of tissue to be able to make a diagnosis. In this case, a new biopsy will be required.

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In ____________________, on _____of_______ in______

Patient signature ________________________________
Gynaecologist signature ________________________________

www.igenomix.com
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