

MicroSort

Division of the Genetics & IVF Institute

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AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

As part of this study, the MicroSort[®] Division at Genetics and IVF Institute (GIVF) will keep records of your participation in the study. These study records will include information about procedures and tests you have during the study or had before the study, and other medical information about your participation in this study. Under federal law your study records cannot be used or shared by GIVF for research purposes unless you sign this authorization (permission form). *You may not participate in the study unless you sign this authorization.* If you sign it, you will be agreeing to let other people look at and use your health information as described below:

- Some or all of the test results and other information will be reviewed and kept by GIVF (the sponsor of this study), and other people and companies (called consultants) who are helping GIVF conduct the study. GIVF and its consultants will examine these results and information and may report them to the U.S. Food and Drug Administration (the FDA) or similar agencies in foreign countries. Your study records will be assigned a code number by the study team and your name will ordinarily not be in the study records that are sent to the FDA. However, GIVF and its consultants will have the right to see your complete study records, including your name, as well as your medical records. Representatives of the FDA may also review your medical records.
- GIVF may publish reports or articles on the study. However, your name will not be in any published reports or articles written by GIVF or any study investigator.
- In addition, employees of GIVF and its consultants will be reviewing the study to ensure it is being run correctly, and they will look at your study records and your medical records for this purpose.
- Doctors and other health care providers other than those at GIVF that treat you while you are in this study [or that treated you before you joined the study] may share your medical records with GIVF to look at during this study.
- Your study records and medical records may also be looked at by GIVF's Institutional Review Board, which is a committee that makes sure that all human research studies at GIVF are run safely and fairly.

GIVF and GIVF's Institutional Review Board will look at and use your study records only for purposes of this study. They will keep your identity secret and, except for the sharing of your information described above, will not let other people look at your study records unless required by law. Once GIVF shares your information with its consultants, the information will no longer be protected by federal privacy protection laws. However, GIVF and its consultants will only use your information for purposes of the study and will not share your study records with people other than the FDA and similar government agencies, unless required by law. Your study records will be kept at GIVF indefinitely following the completion of the study. You will not have the right to see your study records while the research is going on. However, you will be able to see your records after the research has been completed.

This authorization will not expire (stop on its own). However, you have the right to cancel this authorization at any time. You can do this by writing to GIVF, telling them that you are canceling your authorization to use and share medical information. Cancellation of authorization should be sent to

MicroSort[®] Regulatory Office
3015 Williams Drive
Fairfax, VA 22046

If you send a letter canceling this authorization to use and share your medical information, you will not be allowed to stay in the study after GIVF receives your letter.

If you drop out of the study, you do not have to cancel your authorization to use and share your medical information. However, if you drop out of the study and do decide to cancel your authorization to use and disclose your medical information, the information that has already been collected by GIVF may continue to be used and shared as described above, but only as necessary to protect the integrity of the research project.

You have a right to receive a copy of this form.

Authorization

I have read this Authorization to Use and Disclose Medical Information and understand it. I give permission for the use and sharing of my medical information as described above.

Name [Wife]

Date

Name [Husband]

Date