

ADVANCED FERTILITY SERVICES

IN VITRO FERTILIZATION CENTER

INFORMATION AND CONSENT FORM

THE INTRAOVARIAN INJECTION OF AUTOLOGOUS (YOUR OWN) PERIPHERAL BLOOD MONONUCLEAR CELLS, PLATELETS, AND BLOOD SERUM GROWTH FACTORS (PBMNC) FOR THE RECREATION OF OVARIAN FUNCTION

BACK GROUND AND GENERAL INFORMATION

THE USE OF DONATED EGGS OR ADOPTION ARE CURRENTLY THE ONLY VIABLE OPTIONS FOR MENOPAUSAL OR INFERTILE PERIMENOPAUSAL WOMEN TO HAVE A BABY. BOTH ARE COSTLY (\$20,000-\$50,000), EMOTIONALLY DIFFICULT, AND MAY NOT BE ACCEPTABLE TO MANY COUPLES ON EMOTIONAL OR RELIGIOUS GROUNDS. RECENTLY, HOWEVER, THERE HAVE BEEN TWO CASE REPORTS OF SUCCESSFUL CONCEPTIONS IN MENOPAUSAL WOMEN, USING VERY DIFFERENT TECHNIQUES, TO "REAWAKEN" OR "REJUVENATE" THE HUMAN OVARY'S ABILITY TO PRODUCE VIABLE EGGS. A GROUP OF DOCTORS IN JAPAN (KWAMAMURA, 2013) SURGICALLY REMOVED THE OVARIES OF THE WOMEN WITH PREMATURE OVARIAN FAILURE (MENOPAUSE), CUT THEM INTO SMALL STRIPS, FROZE THE TISSUE IN LIQUID NITROGEN AND THEN REIMPLANTED THE OVARIAN TISSUE BACK INTO THE PATIENT. THE OVARIAN TISSUE THEN PRODUCED EGGS AND ONE CONCEPTION HAS BEEN REPORTED. USING A COMPLETELY DIFFERENT TECHNIQUE (ALI, 2013), THE CONCEPTION AND DELIVERY OF HEALTHY BABY IN A 49 YEAR OLD MENOPAUSAL WOMAN WAS PUBLISHED BY AN ACADEMIC MEDICAL GROUP IN EGYPT. THIS GROUP INJECTED THE WOMAN'S OVARIES WITH HER OWN WHITE BLOOD CELLS, RESULTING IN THE REVERSAL OF MENOPAUSE, THE REOCCURRENCE OF EGG PRODUCTION AND CONCEPTION. ALTHOUGH THE METHODOLOGIES REPORTED ARE TOTALLY DIFFERENT, BOTH DEMONSTRATE THAT THE HUMAN OVARY IS CAPABLE OF REGENERATION WITH RESPECT TO EGG PRODUCTION. THESE STUDIES SUGGEST POSSIBILITIES THAT ARE TOTALLY DIFFERENT FROM OUR CURRENT CORE BELIEFS REGARDING FEMALE REPRODUCTION, WHICH STATES THAT A WOMAN IS BORN WITH ALL THE EGGS THAT WILL BE AVAILABLE THROUGH HER REPRODUCTIVE LIFETIME. CONSEQUENTLY WHEN A WOMAN'S EGGS ARE USED UP, NO MORE CAN BE MADE.

THESE STUDIES SUGGEST THAT SOME POSTMENOPAUSAL OVARIES MAY ACTUALLY CONTAIN IMMATURE EGGS CELLS OR STEM CELLS THAT CAN BE MORPHED INTO EGGS, WHEN ACTIVATED BY AN APPROPRIATE BIOLOGICAL STIMULUS. STEM CELLS, WHICH ARE CAPABLE OF DEVELOPING INTO AN INFINITE VARIETY OF BODY TISSUES, ARE AT THE CORE OF HUMAN EMBRYONIC DEVELOPMENT. THEY ARE THE CELLS THAT ULTIMATELY DEVELOP INTO THE ORGAN SYSTEMS THAT MAKE UP THE HUMAN ORGANISM. STEM CELLS HAVE BEEN SHOWN TO BE PRESENT IN MANY DIFFERENT TYPES OF HUMAN TISSUES, INCLUDING THE OVARIES AND MAY GROW INTO HEALTHY ADULT CELLS UNDER CERTAIN BIOLOGICAL CONDITIONS. ADULT TISSUE STEM CELLS MAY POTENTIALLY SERVE AS THE WAY THAT THE BODY CAN REPAIR ITS OWN INJURED OR POORLY FUNCTIONING TISSUES. THE ACTIVATION OF STEM CELLS TO STIMULATE THE HEALING PROCESS BY INJECTING COMPONENTS OF A PATIENT'S OWN BLOOD INTO AN INJURED AREA HAS BEEN SUCCESSFULLY AND SAFELY USED IN FOR OVER TEN YEARS TO SPEED THE HEALING OF THE BONE, SKIN SPORTS INJURIES. SINCE THE STEM CELL ACTIVATOR IS MADE FROM THE PATIENTS OWN BLOOD, IT IS EXTREMELY SAFE, DOES NOT INVOLVE SYNTHETIC DRUGS OR CHEMICALS, ELIMINATES IMMUNOLOGIC AND ALLERGIC REACTIONS, OR RISKS OF VIRAL INFECTIONS THAT ARE ASSOCIATED WITH BLOOD TRANSFUSIONS. COMPLICATIONS FROM THIS PROCEDURE ARE RARE IN THE WORLD'S MEDICAL LITERATURE, BUT THE COMPLICATIONS OF INFECTION AND BLEEDING MAY BE RESULT FROM MEDICAL PROCEDURE.

DESCRIPTION OF THE EXPERIMENTAL PROCEDURE FOR OVARIAN REJUVINATION FOR THE POTENTIAL RESTORATION OF OVULATION AND FERTILITY

THIS PROCEDURE WE WILL PERFORM IS BASED UPON THE CASE REPORT PUBLISHED BY DR. ALI IN JUNE OF 2013. WE WILL FOLLOW HIS PROTOCOL FOR THE PREPARATION OF THE STEM CELL/PRIMORDIAL EGG CELLS STIMULATING AGENT WAS INJECTED INTO THE PATIENT'S OVARIES USING A SURGICAL TECHNIQUE CALLED LAPAROSCOPY, WHICH REQUIRES GENERAL ANESTHESIA. WE WILL INJECT THE ACTIVATING AGENT NON-SURGICALLY, THROUGH THE VAGINA UNDER PROPOFOL ANESTHESIA, USING AN ULTRASOUND GUIDED NEEDLE. THIS BASICALLY THE SAME PROCEDURE THAT IS USED TO HARVEST EGGS DURING AN IN VITRO FERTILIZATION PROCEDURE. COMPLICATIONS RESULTING FROM THIS PROCEDURE ARE BASICALLY SIMILAR TO THOSE EXPERIENCED AS RESULT OF IVF EDD RETRIEVAL. THEY ARE INTERNAL BLEEDING, INFECTION, PERFORATION OF INTERNAL ORGANS, OVARIAN PAIN, VAGINAL PAIN OR BLEEDING. ALTHOUGH SUCH COMPLICATIONS ARE RARE, HOSPITAL ADMISSION, REPARATIVE SURGERY, LOSS OF ONE OR BOTH OVARIES, ANESTHETIC COMPLICATIONS AND DEATH ARE POSSIBILITIES.

ADVANCED FERTILITY SERVICES

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IN VITRO FERTILIZATION CENTER

WE STATE CLEARLY THAT INTRAOVARIAN INJECTION OF PBMNC OR ANY OTHER TYPE OF PLATELET DERIVED GROWTH FACTORS MADE FROM THE PATIENTS OWN BLOOD IS PURELY EXPERIMENTAL. IN ACCEPTING TO DO THIS PROCEDURE, YOU FULLY REALIZE AND ACCEPT ITS EXPERIMENTAL NATURE AND UNDERSTAND THAT NO STATISTICS OR INFORMATION IS AVAILABLE OTHER THAN THE ONE PUBLISHED CASE REPORT IN THE MEDICAL LITERATURE, WHICH HAS NOT BEEN REVIEWED BY ANY MEDICAL OR SCIENTIFIC REVIEW BOARD IN THE UNITED STATES. YOU FURTHER UNDERSTAND THAT THERE IS NO IMPLIED GUARANTEE THAT THIS PROCEDURE WILL HELP YOU BECOME PREGNANT. YOU FURTHER UNDERSTAND THAT OVULATION RATES, PREGNANCY RATES, MISCARRIAGE RATES, LONG TERM COMPLICATION RATES, ANOMALY ("BIRTH DEFECT") RATES, PREMATURE OR TERM PREGNANCY RATES OR THE INCIDENCE OF BEHAVIORAL OR DEVELOPMENTAL DEFECTS IN OFFSPRING RESULTING FROM PREGNANCIES ARE NOT KNOWN AT THIS TIME. YOU THEREFORE AGREE TO HOLD DR. MELNICK, AND ANY OTHER PHYSICIAN OR PERSONNEL EMPLOYED BY ADVANCED FERTILITY SERVICES, P.C. HARMLESS SHOULD YOU SHOULD FAIL TO CONCEIVE OR IF ANY ADVERSE, HARMFUL OR UNDESIRABLE EFFECTS OR OUTCOMES SHOULD OCCUR. A FEE OF \$4,000.00/ PER PROCEDURE INCLUDES BLOODS DRAWING, THE KITS, REAGENTS AND LABOR INVOLVED IN THE PBMNC SEPARATION, ANESTHESIA. THE TRANSVAGINAL INTRAOVARIAN INJECTION OF YOUR PBMNCs, OPERATIVE SUPPLIES AND FEES AND RECOVERY ROOM MEDICATIONS AND CARE.

I _____ HAVE BEEN SEEN THOROUGHLY AND ADEQUATELY COUNSELED BY DR. MELNICK, AND/OR ANOTHER PHYSICIAN OR MEMBER OF THE ADVANCED FERTILITY SERVICES STAFF ABOUT MY CURRENT OVARIAN STATUS AND I UNDERSTAND THAT I HAVE LITTLE CHANCE OF CONCEIVING NATURALLY. I HAVE BEEN GIVEN ALTERNATIVE CHOICES, INCLUDING THE USE OF DONOR EGGS, ADOPTION AND REMAINING CHILDLESS. THE PROCEDURE OF THE INTRAOVARIAN INJECTION OF PERIPHERAL MONOCYTES FOR IMPROVEMENT OF OOCYTE RESERVE HAS BEEN FULLY EXPLAINED TO ME AND ALL MY QUESTIONS ABOUT IT HAVE BEEN FULLY ANSWERED. I FULLY UNDERSTAND THE RISKS INVOLVED IN THIS PROCEDURE AND ALL INFORMATION CONTAINED IN THIS CONSENT FORM. I HAVE BEEN CLEARLY INFORMED OF THE EXPERIMENTAL NATURE OF THIS PROCEDURE, BUT WISH TO ASSUME ALL RISKS OF SUCH PROCEDURE SINCE I ONLY WISH TO CONCEIVE USING MY OWN EGGS. THEREFORE I AM WILLING TO PARTICIPATE IN THIS EXPERIMENTAL

PROCEDURE AT MY OWN RISK AND EXPENSE WITH NO GUARANTEES OF SUCCESS OR THE NATURE OF THE OUTCOME AS DETAILED IN THIS CONSENT.

I FURTHER REALIZE THAT ADDITIONAL FERTILITY TESTS AND TREATMENTS SUCH AS BLOOD TESTS, ULTRASOUNDS, TUBAL SURGERY, FERTILITY MEDICATIONS WITH OR WITHOUT INTRAUTERINE INSEMINATION OR IN VITRO FERTILIZATION, AS WELL AS ADDITIONAL OFFICE VISITS AND COUNSELING MAY BE NEEDED TO ACHIEVE PREGNANCY AFTER THIS PROCEDURE HAS BEEN PERFORMED. AGAIN I ACKNOWLEDGE AND UNDERSTAND THAT THERE IS NO ACTUAL OR IMPLIED REPRESENTATION MADE THAT THIS PROCEDURE WILL RESULT IN A PREGNANCY OR THE LIVE BIRTH OF A HEALTHY CHILD.

I _____ AGREE TO ALL TERMS AND UNDERSTAND ALL INFORMATION IN THIS CONSENT FOR INTRAOVARIAN PBMNC INJECTION AND AGREE TO HOLD DR. MELNICK, AND ANY AND ALL OTHER PHYSICIANS OR OTHER PERSONNEL OF ADVANCED FERTILITY SERVICES HARMLESS FOR ANY MANNER OF IMMEDIATE OR DELAYED ADVERSE OUTCOME TO ME OR TO THE RESULTING CHILD.

PATIENT _____ DATE _____

WITNESS _____ DATE _____

PHYSICIAN _____ DATE _____

HAVE READ THE ABOVE INFORMATION AND CONSENT: INTRAOVARIAN INJECTION OF PERIPHERAL BLOOD MONOCYTES FOR THE INTENTION OF IMPROVING OOCYTE (EGG) RESERVE, HAVE HAD ALL QUESTIONS ANSWERED, AND FULLY UNDERSTAND THE ENTIRE CONTENT OF THE CONSENT AND AGREE WITH ALL POINTS RAISED.

I ALSO HAVE BEEN COMPLETELY AND ADEQUATELY COUNSELED BY DR. MELNICK, AND OR ANOTHER PHYSICIAN OR MEMBER OF THE ADVANCED FERTILITY STAFF.

PATIENT _____ DATE _____

