FINANCIAL COMMITMENTS
No Additional Costs To Participate

Patients who are randomized to the CCS group will receive embryonic aneuploidy screening (CCS) free of charge and will not be charged for additional blood work or genetic analysis of the conceptus. Patients in the control group will have no alterations in any aspect of their care and thus will not incur any additional expenses.

Patients will be billed in the usual manner for screening, diagnostic costs, and routine IVF cycles from Reproductive Medicine Associates as they would normally be billed if they were not participating in this study.

If cryopreservation of the embryo is medically indicated in the current cycle, the cost associated with the frozen embryo transfer (FET) will be covered under the study. FET cycle medications will need to be purchased. The monitoring (blood work and ultrasound) costs of the subsequent cryosynthetic cycle will be covered provided the cryosynthetic cycle immediately succeeds the present cycle.

Patients will be required to pay a fee for anesthesia during the oocyte retrieval. Patients who wish to maintain embryos in cryopreservation will have to pay a standard annual storage fee.

HOW CAN YOU LEARN MORE?

Please let your doctor or nurse know if you would like more information or have any questions. You can also contact the Clinical Research Team directly at 973-656-2841 or clinicalresearchteam@rmanj.com
The objective of the SOLAIRE clinical trial is to assess the impact of comprehensive chromosomal screening (CCS) on patients with low ovarian reserve in an effort to improve success during in vitro fertilization (IVF) and decrease the time to successful pregnancy.

ELIGIBILITY
- Anti-Mullerian hormone (AMH) level ≤ 1.1 ng/mL, tested within previous year
- Total basal antral follicle count less than or equal to eight
- Male partner with >100,000 total motile spermatozoa per ejaculate (donor sperm acceptable)

BACKGROUND
Reproductive aging is due principally to changes in the available pool of eggs in the ovary. As reproductive aging occurs the number of eggs decreases and the proportion of those eggs which are of high quality greatly decreases. The decrease is most typically seen in patients in the mid to late 30s but does happen earlier. This decrease is called diminished ovarian reserve, and these patients are “low responders” in terms of quantity of eggs when IVF is undertaken.

While the quantity of eggs may present a problem in low responders, the quality of those eggs is also of great concern. Quality of eggs is primarily driven by whether or not they have the correct genetic material. Low responders are more likely to produce aneuploid (the incorrect amount of DNA) embryos. These embryos most frequently result in early failure or miscarriage of the pregnancy and often prolong the time until the next attempt may be undertaken.

With the effectiveness and utility of CCS having been well established in several large randomized controlled clinical trials, the use of CCS in patients with low ovarian reserve has not been fully studied.

STUDY DESIGN
All care, up through the blastocyst stage of embryonic development, will be completely per routine RMA practice standards and protocols. Once at the blastocyst stage of development, patients will be randomized to either the study group which will receive CCS as part of their protocol or the control group which will not.

Within the study group, embryos will undergo biopsy per standard laboratory protocol and the cells placed into lysis buffer. CCS will be done by the genetics laboratory and the results made available prior to transfer. Only euploid embryos will be selected for transfer. As per routine in this program, no more than two embryos will be transferred. Any supernumerary embryos which are euploid will be cryopreserved for future use.

Within the control group, patients will undergo embryo transfer without CCS. As per routine care at RMANJ no more than two embryos will be transferred. Any supernumerary embryos will be cryopreserved for future use.