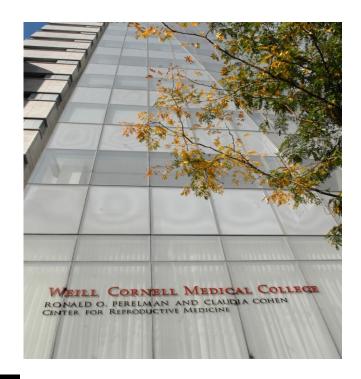
Introduction to CRM

Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine - CRM



CRM Locations

Upper East Side (Main Office) 1305 York Avenue, 6th Floor New York, NY 10021

Garden City, Long Island 1300 Franklin Avenue Garden City, NY 11530

open 7 days a week - 6:30 - 8:30am

Upper East Side (Satellite Office)
215 East 68th Street
New York, NY 10065
(no monitoring at this site – satellite for Dr. Melnick)

Mount Kisco, Westchester County 657 Main Street Mount Kisco, NY 10549

Tribeca255 Greenwich Street, Suite 540
New York, NY 10007

Upper West Side
2315 Broadway (corner of 84th and Broadway)
New York, NY 10024
(no monitoring at this site – satellite for Dr. Goldschlag)

Monitoring hours for each location available on the CRM website www.ivf.org and included in the orientation packet



The CRM Clinical Team

13 Attending Physicians

Each manage independent practices and office hours
Contribute to monitoring sessions at all sites
Rotate coverage in the IVF operating room

Fellowship Program for REI

3 year fellowship program that follows completed Obstetrical & Gynecology Residency Support the physician team with monitoring and office hours

Nursing Teams — (LPN's RN's, NP's and PA's)

Work collaboratively with CRM physicians
Work as teams to provide 7 day coverage
Support patient clinical and educational needs

Support Staff

Medical & Ultrasound Technicians





What is Fertility Preservation?

A treatment plan that includes the administration of fertility medications (gonadotropins) to stimulate the development of multiple eggs (follicles) in the ovaries

Using both bloodwork and ultrasound evaluation, the follicles (fluid filled sac) are evaluated for development and maturity

Once the recruitment process meets criteria for retrieval, the "eggs" are surgically retrieved from the ovaries in a transvaginal procedure under ultrasound guidance in the IVF operating room

Patients then elect to "cryopreserve" or freeze the eggs (oocytes) or embryos retrieved for use in the future



Treatment Timeline

- I. Initial Consultation
- II. Orientation Class
- III. Required Pre-testing
- IV. Visits with Psychologist
- V. Getting Started
- VI. Stimulation and Monitoring
- VII. Retrieval
- VIII. Planning to Use the Cryopreserved Oocytes
- IX. Consent Process
- X. Follow-up Management



Initial Consultation

Goal: The Reproductive Endocrinologist collects a medical, surgical and reproductive history. The consultation allows for a comprehensive evaluation of the factors that impact fertility, fertility preservation, endocrine factors, genetics, anatomical or structural findings as well as age related implications.

Additional Considerations:

- GYN history
- Testing or surgical recommendations before treatment

Conclusion:

- Provide a plan of care with treatment options
- Review consents and risks vs. benefits.
- Outline plan for next steps
 - Participation in orientation class and injection training
 - Required pre-testing





Orientation Class



Required part of the program at CRM:

Aim:

- Review specific insurance implications and the potential out-of-pocket expenses
 generally not covered by managed care check individual policy
- Provide and explanation of the "timeline" of treatment
- Clinical treatment options
- Retrieval considerations
- Review medication and administration techniques
- Discussion related to required consent process
- Meet 1-1 with an nurse coordinator to review plan, estimated timing, outstanding testing





Required Prerequisite Testing

Patient:

Comprehensive panel of lab work including:

- Hormone evaluations
- Infectious disease screening (annual)
- Comprehensive Chemistry Panels
 - Evaluates general health
- Cervical cultures (annual)
- HSG (Hysterosalpingogram) and/or SIS (Saline Infused Sonogram)
 - Evaluates fallopian tubes and uterus
- Genetic Evaluations
- Ultrasound and uterine assessment
- Psychologist visit



Getting Started

Contact your primary nurse coordinator on CD 1-3 of the month prior to the planned cycle (day 1 defined as the 1st day of full menses)

- Some medication protocols begin in the cycle preceding start
- Nursing team will provide an <u>estimated</u> timeline

Business and personal travel plans must be avoided during stimulation

On the assigned "start day":

- Come to the office for baseline bloodwork and ultrasound
- Meet with Research Coordinator for consent review
- Meet with an IVF nurse to review:
 - medication protocol
 - medication needs
 - instructions for starting medications

Monitoring hours at Main Office location: 6:30am – 8:30am

Satellite offices are posted on the locations slide and found on CRM website: www.ivf.org





Stimulation and Monitoring

Stimulation

- Injectable medications stimulate the production of follicles in the ovary (follicle(s) are fluid filled sacs that may contain an "egg")
- Medication instructions provided in the evening of monitoring days
- Generally 8-14 days of sub-cutaneous injections
 - 2-3 injections daily
 - Dosing based on monitoring results
- Recommend taking as close to same time each day (7pm -10pm)
- Refrain from high-impact exercise, aerobics, pelvic twisting
 - Walking and acupuncture permitted
- No ibuprofen (Advil or Motrin products) or aspirin (unless instructed)
 - TYLENOL ONLY
 - No herbs or supplements (PNV permitted)

Common Side effects:

- Bruising or discomfort at injection sites
- Bloating and/or weight gain
- Mood swings
- Fatigue
- Headaches

Monitoring

- Near daily monitoring for bloodwork and or ultrasound is expected
- Ultrasounds performed by a CRM physician or Ultrasound techs
- Generally 8-14 days in total
- Each day that monitoring is performed nursing will call with instructions by 6:30pm
 - Please have an "identifying message" on voicemails
 - Ensure that voicemails are set-up and clear to accept to accept messages

Office hours differ by location – refer to CRM website

NOTE: Only the NYC Main office is open on weekends & holidays

Recommendation:

Medication Log:

- Ensures supplies meets individual needs
- Refills are sent to all pharmacies upfront to avoid the need for additional medication requests



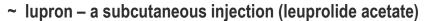


Taking the "trigger shot"

Based on ultrasound and bloodwork evaluation, the team determines timing for the "trigger" shot.

The "trigger" is given as:

~ hCG - an intramuscular injection (human chorionic gonadotropin) OR









Clear dosing instructions will be provided

Medications are ordered in advance to the pharmacy - be sure it is included in the shipment

Timing is **VERY** specific – critically important to take at the assigned time (9pm-2am)





Morning after the "trigger shot"

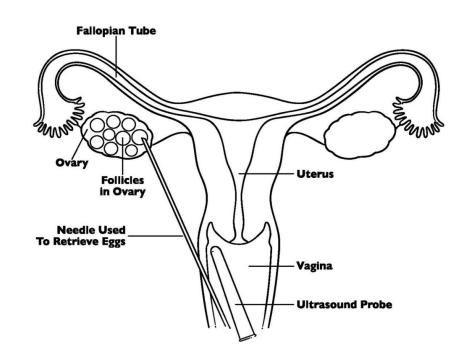
MANDATORY PRE-OP: 1305 York Ave. location – 6:30 am to meet with IVF Team

- Bloodwork drawn
- Complete required hospital paperwork
- Complete NYP procedure consents for retrieval
- Obtain instructions hospital admission for the following day
- Review post-retrieval management and timing



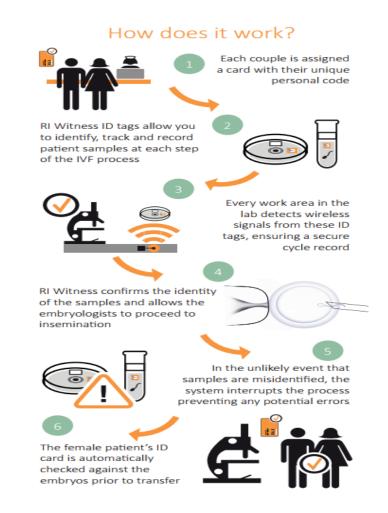
Egg Retrieval

- Admission to New York Presbyterian M8 IVF
- Performed trans-vaginally with ultrasound guidance
- Vaginal prep done in procedure room
- Physicians rotate coverage daily
- IV sedation given for procedure
 - Conscious sedation Wake up quickly
 - Given for comfort and safety
 Notify nursing of any prior anesthesia complications
- Procedure takes approximately 15 minutes
 - Followed by transfer to recovery ~ 1 hour
- Eggs are retrieved in the OR and taken to the embryology lab for fertilization



Electronic Witness

- To further provide our patients the highest quality care, the Center for Reproductive Medicine has implemented Electronic Witness (EW) as part of their IVF Lab procedures.
- EW offers patients added security to their samples through the use of radio frequency ID technology to further guard against any potential mix-ups that could occur.
- This added layer of protection will be used in conjunction with the employee witnesses and verification that already occurs within the IVF Lab.
- All current and new patients will be assigned a card with a unique personal code to begin the process.



Discharge from NYP

Discharge Instructions for M8:

- Comprehensive instructions provided upon discharge
- Rest at home for the rest of the day
- Mild cramping, discomfort and spotting is common
 - Tylenol ONLY for discomfort
 - No ibuprofen or aspirin
- Contact CRM for:
 - extreme pain
 - heavy bleeding
 - Inability or lack of urination
 - fever >101°
- Avoid placing anything vaginally (tampons, douching, intercourse)
 - Recommend avoiding tub baths and swimming
- Oral medication instructions will be provided for:
 - Medrol (methylprednisolone)
 - Z-pack (azithromyicin)

NYP policy requires all patients be discharged with an adult escort



Day After the Retrieval

- An IVF nurse will call with the following information:
 - Total number of eggs (oocytes) retrieved
 - Number of eggs mature and immature
 - Number of eggs frozen cryopreserved

- Possible Side Effects:
 - Vaginal spotting light bleeding
 - Mild cramping or soreness
 - Mild bloating which will resolve after procedure

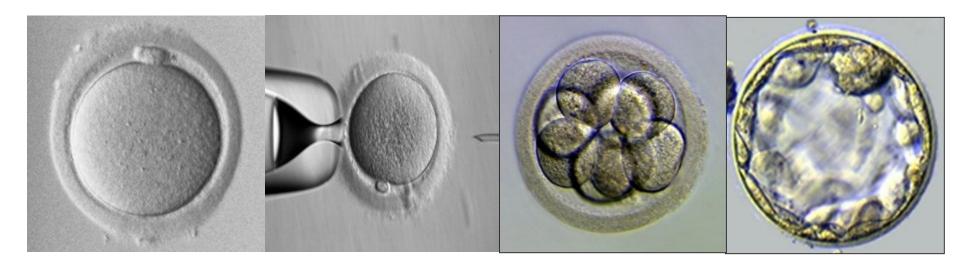


Cryopreservation of Oocytes

- "Eggs" (oocytes) are frozen the same day as the retrieval
- Freezing process is called "Vitrification"
 - Rapid freezing technique
 - Used for both eggs and embryos
- Eggs stored in the laboratory for future use
 - Subject to quarterly storage fees
 - 1st Six months storage included



Using the Cryopreserved Oocytes



Using the Cryopreserved Oocytes

- Consultation with CRM physician:
 - Update required testing
 - Ultrasound evaluation
 - Consent requirements
- Determination of Sperm Source:
 - Partner Fresh or Frozen
 - Donor Samples from Commercial Bank
 - Additional information available
- Intracytoplasmic Sperm Injection
 - ICSI method used for fertilization in the lab

- Frozen Embryo Cycle Options:
 - Natural no injectable medications
 - Timing with bloodwork and ultrasound
 - Plan thawing of eggs and sperm sample according to "natural" cycle
 - Schedule transfer accordingly
 - Programmed with medications (irregular cycles)
 - Estrogen patches to "create" a cycle
 - Plan thawing of eggs and sperm sample according to "timed" cycle
 - Schedule transfer accordingly



Clinical and Research Consents

Consents for Treatment

CRM Consents:

- Treatment Consents reviewed with physician at consult and Research Team available for questions
 - Must be completed and submitted on the 1st day of cycle
 - Required consents include:
 - IVF Treatment Consent
 - Cryopreservation
 - requires determination of "disposition" of oocytes
 - discard, donate to another person (FDA screening required), donate to research, or transfer oocytes to another center for storage
- Research Consents
 - Patient participation is voluntary
 - Relate to research studies currently active at CRM
 - Consent obtained in the presence of a CRM Research Coordinator



Medication and Injection Planning

Medication Protocol

Following the Orientation Class: Meet 1:1 with an IVF coordinator to review plan, timing and medication needs

PRIOR AUTHORIZATION MAY BE REQUIRED

CONTACT INSURANCE BEFORE FILLING PRESCRIPTIONS

Failure to secure this information CAN impact your out-of-pocket expenses

- Confirm pharmacy location to fill prescriptions
 - May require one pharmacy for injectable needs and one for other prescriptions
- Clarify the in-network (insurance coverage) FSH (Gonal-f or Follistim) and antagonist

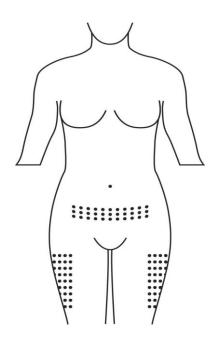
NOTE: patients must confirm fertility coverage (treatment & medication) prior to starting treatment nursing cannot process the prior authorization



Injections Sites

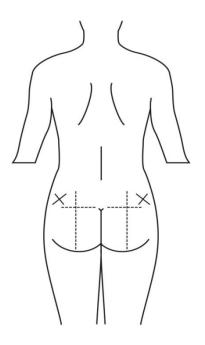
Subcutaneous Sites (sub-q):

- Location for medications used for stimulation
- Rotate sites as highlighted
- Sub-q sites for "daily" injections



Intramuscular Sites (IM):

- Used for hCG and progesterone injections
- Upper-outer quadrant of the butt
- Rotates sides each night





Sharps Disposal

Disposal Guidelines:

- Regulated biohazard sharps containers available at pharmacy
 - Puncture-proof containers only (as shown)
 - No needles can go in regular garbage
 - No alternative containers
- Sharps containers can be discarded at CRM
 - Never in regular garbage



Preparing for Daily Injections

Supplies:

- Alcohol wipes
- Gauze pads
- Antibacterial hand soap or hand sanitizer
- Sharps container
- Clean area for preparation and injection

Medications:

- Ensure medication inventory matches nursing instructions
- Review refill status on orders (additional medication and supplies are at pharmacy
- Check that all needle supplies match needs
- Refrigerate medications as required



Medication Injection Training

Training will be presented at the class

- Both subcutaneous and intramuscular techniques
- Additional support is available on-line at Freedommedteach.com

Plan Ahead

- Select a time for nightly injections between 7pm and 10 pm
 - As close to same time each day as possible
- If assistance with injections is needed anticipate needs
- Business and personal travel plans should be avoided during stimulation
- Refrigeration requirements for medications



Psychological Support Services

The CRM clinical team recognizes and supports the impact that fertility treatment has on both your personal and professional life.

Specially trained psychologists are on staff and available for appointments – (646) 962-2764

Tuesday Morning "Women's Drop-In Group"

Free support group offered every Tuesday morning at 9am

Located in the main office

no appointment necessary





Reference Web Sites

- CRM site <u>www.ivf.org</u>
- Resolve Advocacy Organization <u>www.resolve.org</u>
- Injection references:
 - Freedom Pharmacy page <u>www.freedommedteach.com</u>
 - Ferring Pharmacy page <u>www.ferringusa.com</u>
 - Include training videos
 - Reconstitution and injection techniques

Fertility Preservation Program Specialist: Bridget Wahmann (646) 962-5450





Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine

"We are passionate about helping our patients become parents"

Dr. Zev Rosenwaks

Director and Physician-in-Chief, Ronald O. Perelman and Claudia Cohen Center for Reproductive Medicine



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