

Introduction to CRM

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Center for Reproductive Medicine - CRM



CRM Locations

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

open 7 days a week – 6:30 - 8:30am

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

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

Tribeca
255 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 In Vitro Fertilization (IVF)?

- 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, the follicles (fluid filled sac that may contain an egg) 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
- Embryo(s) are then created in the embryology lab using the retrieved eggs and sperm
- Embryo(s) are evaluated and selected for transfer back into the uterus 3 or 5 days later

Treatment Timeline

- I. Initial Consultation
- II. Orientation Class
- III. Required Pre-testing
- IV. Getting Started
- V. Stimulation and Monitoring
- VI. Retrieval and Transfer
- VII. Post-Transfer Management
- VIII. Consent Process
- IX. Follow-up Care

Initial Consultation for Infertility

Goal: The Reproductive Endocrinologist collects a medical, surgical and reproductive history from both the patient and partner, if applicable. The consultation allows for a comprehensive evaluation of the factors that impact fertility including both female and male considerations, endocrine factors, genetics, anatomical or structural findings as well as age related implications.

Additional Considerations:

- Infertility history
- Prior treatment successes and failures
- 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
- Provide and explanation of the "time-line" of treatment
- Clinical treatment options
- Retrieval and transfer considerations
- Review medication and administration techniques
- Discussion related to required consent process
- Meet 1-1 with an infertility nurse coordinator to review plan, 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)
- Uterine sounding (if applicable)
- HSG (Hysterosalpingogram) and/or SIS (Saline Infused Sonogram)
 - Evaluates fallopian tubes and uterus
- Genetic evaluations
- Ultrasound and uterine assessment

Male Partner: (if applicable):

Lab work:

- Infectious disease screening (annual)
- Genetic evaluations
- Semen analysis to evaluate sperm concentration, volume, count, morphology and motility

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 *estimated* 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
- 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:

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



Sperm Source Considerations

Fresh Semen Sample:

- Produced the day of retrieval on the IVF Suite at NYP
- Second samples may be requested by lab
- Specific arrival times are provided
- Shower with an antibacterial soap morning of sample

Frozen Semen Sample:

Partner:

- Cryopreserved in anticipation as back-up
- Surgically retrieved in the past

Donor:

- Used as up-front use or back-up
- Transferred to CRM andrology lab from commercial labs
 - Shipments accepted Monday – Thursday
 - Contact Andrology lab (646) 962-8448
- **Must** be at CRM prior to starting stimulation
- Nursing team will need:
 - Name of the donor sperm bank
 - Donor ID number
 - Number of vials stored at CRM
 - Recommend 2-4 vials

Recommendations:

- Abstinence period of 2-5 days prior to retrieval (no more than 5)
- Instructions for semen productions provided at pre-op which include antibacterial soap shower on retrieval day
- **Government issued Photo ID is required at the time of sample production**
- If semen production is a concern – notify the nursing team for planning
- It is critical to arrive at your assigned time to ensure the sample is prepared to coincide with the egg retrieval
- Additional consents are required for sperm storage at CRM, the Andrology lab will provide these forms
- Clinical consents and authorization to use frozen samples are required and will be provided

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**
- ~ Lupron – a subcutaneous injection (leuprolide acetate)

OR a combination of both



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)

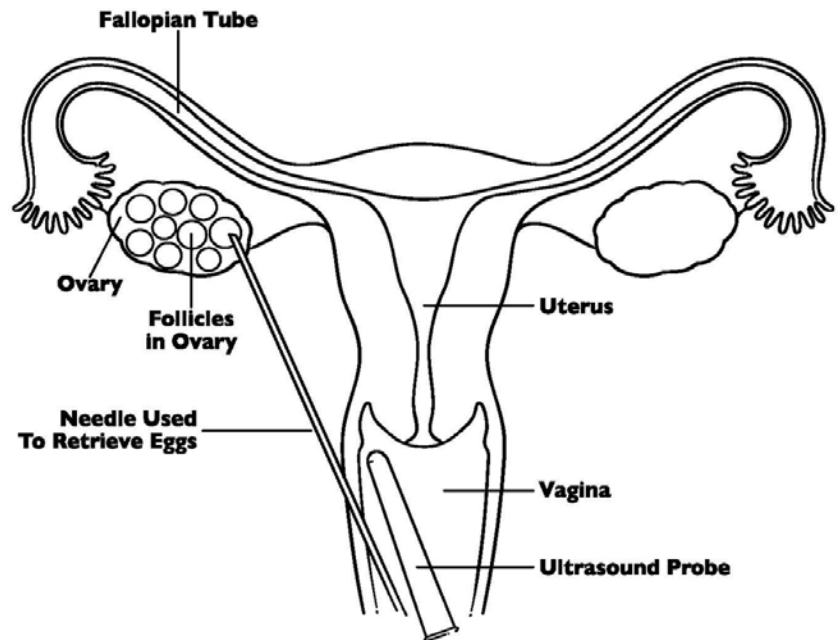
Morning after the “trigger shot”

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

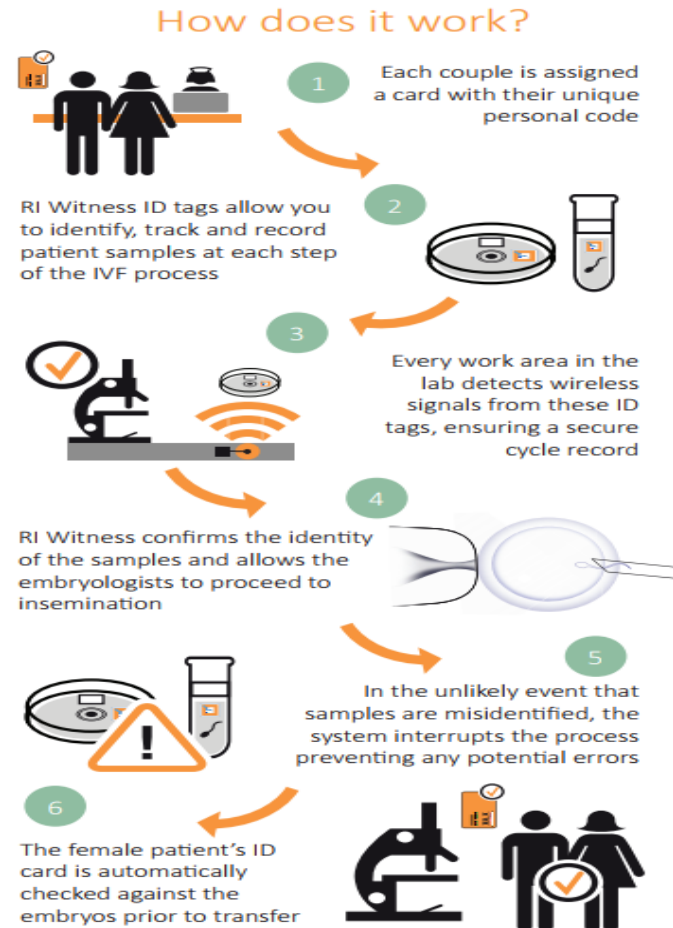
Egg Retrieval

- 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
 - o **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 (azithromycin)

NYP policy requires all patients be discharged with an adult escort

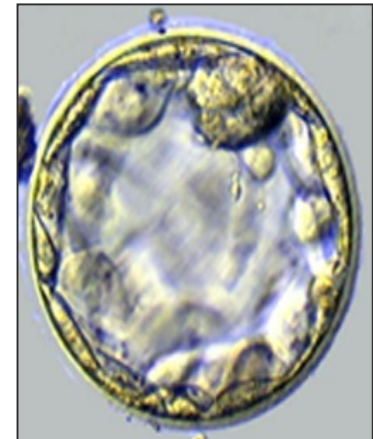
Day After the Retrieval

- An IVF nurse will call with the following information:
 - Total number of eggs (oocytes) retrieved
 - Number mature and immature
 - Number of fertilized embryos
 - Confirm if ICSI was performed
 - Sperm injection – assisted fertilization
 - Provide progesterone instructions
 - Daily intramuscular injection
 - Supports the uterine lining
 - Supports the natural (endogenous) production of progesterone
 - Discuss “planned” transfer schedule
 - Day 3 vs. Day 5
 - Based on embryo development, lab assessment and physician evaluation
- If plan includes retrieval and **NO TRANSFER** (Cryopreservation of oocytes or embryos):
 - Oocytes cryopreservation:
 - Done on day of retrieval
 - No progesterone supplementation
 - Embryo cryopreservation:
 - Done based on plan from physician and lab evaluation
 - Progesterone support may be started – nursing will determine based on plan

Embryo Transfer

Embryo Transfer Plan:

- Discussed with physician in advance
- Transfers are done in the IVF Suite (same location as retrievals)
 - No anesthesia for transfer ~ free to eat and drink before
 - No escort required
- Transfers scheduled as “Day 3” or “Day 5 – Blast”
- Physicians rotate coverage daily
- Criteria for transfer include:
 - Age
 - Quality of embryo(s)
 - Number available for transfer
 - Prior history
 - Genetic results (if available)



Following the Embryo Transfer

After leaving transfer suite:

- Rest for approximately 30 minutes in recovery
- No required bedrest – light, normal activity
- Refer to “Post Transfer Instructions” for next steps and testing dates
- Continue all medications prescribed
 - Only Tylenol for discomfort
 - No ibuprofen or aspirin products

Remaining embryos following transfer:

- Embryology lab will evaluate remaining embryos to determine if they are suitable for cryopreservation
- Embryos that meet the criteria can be frozen (cryopreserved) for future use
- Additional consents are *required* – signed in advance
 - Embryology will confine if embryo(s) are under “observation” and being evaluated
 - Cryopreservation occurs on Day 5 or 6
 - Nursing will notify *only if* embryo(s) were cryopreserved – generally Day 7

Luteal Phase – Embryo Transfer to Pregnancy Test

Luteal Phase blood tests:

- Office Visit for bloodwork on scheduled dates
- Day 24 and Day 26 – Luteal blood work
 - Dates based on a retrieval day 14
 - Testing for Estrogen and Progesterone
 - Nurses will not call with these results
- Pregnancy test Day 28
 - Scheduled date provided
 - Testing schedule Monday through Friday

If the test is positive:

- Instructions for additional bloodwork and ultrasound evaluations will be provided
- Nursing will review medication instructions
 - 4 weeks pregnant at this point
 - Monitoring will continue with IVF team through week 7 – then discharged to OB

If the test is negative:

- Instructions to discontinue medications
- Schedule an appointment with your doctor for a cycle review and plan for next steps



Possible Risks Associated with IVF

- **Ovarian Hyperstimulation Syndrome - OHSS**
 - Occurs when the body “overreacts” to the medication
 - Severe bloating, weight gain, urinary retention, distention
 - Contact the office for any of these symptoms
 - OHSS is rare at CRM
 - Frequent and individualized monitoring
- **Cycle Cancellation**
 - Poor response
 - Convert cycle to IUI
 - Possibly re-cycle with alternative approach
 - Medical issues

Clinical and Research Consents

Consents for Treatment

Three types of consents at CRM:

- **Treatment Consents** – reviewed with physician at consult and Research Team available for questions
 - Must be completed and submitted on the 1st day of cycle
 - Require both partner signatures (where applicable)
 - IVF Treatment Consent - required consent for monitoring and treatment
 - ICSI Consent – sperm injection for assisted fertilization
 - Cryopreservation – freezing of remaining oocytes or embryos
 - Assisted Hatching - day 3 embryo(s) evaluation for “hatching” prior to transfer
- **Research Consents**
 - Patient participation is voluntary
 - Relate to active research studies at CRM
 - Consent obtained in the presence of a CRM Research Coordinator
- **Additional Treatment Consents**
 - Apply to patients requiring additional services or treatments
 - Authorization for Frozen Sperm Use
 - Donor Sperm
 - Religious Observation
 - Pre-implantation Genetic Testing or Screening



Preimplantation Genetic Testing PGD/PGS

PGD and PGS is an optional chromosome analysis of embryos

CRM requires that all patients interested in *OR* considering PGD/PGS meet with a genetic counselor before starting their IVF cycle.

In addition to counseling PGD requires:

- ICSI for insemination
- Special consent forms that patient or couple **MUST** sign in the office
 - cannot be done on day of egg retrieval
- These required consent forms are provided at the counseling session

Preimplantation Genetic Testing PGD/PGS

- ~ Embryos are created on retrieval day (day 0)
- ~ Biopsied on day 5 or 6
- ~ Frozen immediately after biopsy
- ~ Patients are notified on Day 6-7 with the number of embryo(s) biopsied
 - if day 6-7 is a weekend calls are made on Monday
- ~ Embryo(s) remain in storage awaiting test results

Planning for a Frozen Embryo Transfer of tested embryos will be arranged after the genetic counselor has reviewed the results of the biopsy



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

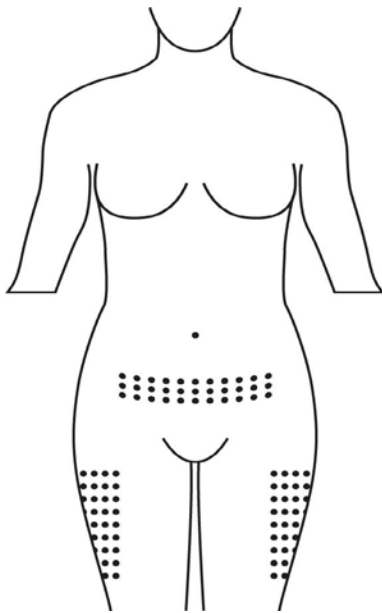
Failure to secure this information CAN impact your out of pocket expenses

- 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

Injections Sites

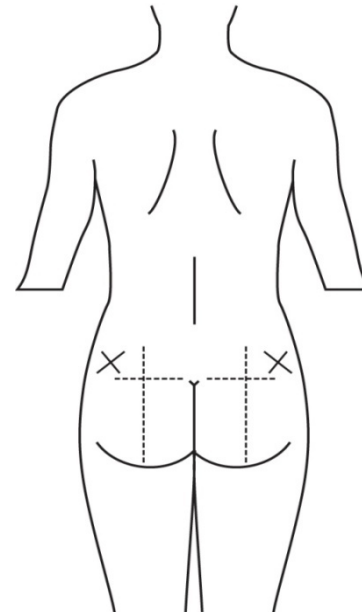
Subcutaneous Sites (sub-q):

- 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
- Band-aides
- 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

- 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 must 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 – www.ivf.org
- Resolve – Advocacy Organization – www.resolve.org
- Injection references:
 - Freedom Pharmacy page – www.freedommedteach.com
 - Ferring Pharmacy page – www.ferringusa.com
 - Include training videos
 - Reconstitution and injection techniques



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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