

Submission Number: 17144

IORG Number: IORG0000124

U.S. Department of Health and Human Services (DHHS)  
Institutional Review Board / Independent Ethics Committee Registration

1. Organization Operating the IRB(s)

Name of Organization: MOUNT SINAI SCHOOL OF MEDICINE

Mailing Address: ONE GUSTAVE L. LEVY PLACE BOX 1075

Street Address: 1425 MADISON AVENUE, ICAHN BUILDING SUITE 4-78

City: NEW YORK

State: NY

Zip Code: 10029-6754

2. Senior or Head Official of Organization Operating the IRB(s)

First Name: DENNIS

Middle Initial: S

Last Name: CHARNEY

Degrees or Suffix: M.D.

Organizational Title: DEAN, MSSM; EXEC VP ACADEMIC AFFAIRS, MSMC

Institution: MOUNT SINAI SCHOOL OF MEDICINE

Telephone: 212 241-5674

Fax: 212 824-2302

E-Mail: DENNIS.CHARNEY@MSSM.EDU

Mailing Address: ONE GUSTAVE LEVY PLACE BOX 1217

ATTENTION: IRB

Street Address:

City: NEW YORK

State: NY

Zip Code: 10029

3. Person Providing This Information

First Name: CAROL

Middle Initial:

Last Name: BIENSTOCK

Degrees or Suffix: CIP, CCRC

Organizational Title: REGULATORY AND ADMINISTRATIVE DIRECTOR

Telephone: 212 659-8980

Fax: 212 876-6789

E-Mail: CAROL.BIENSTOCK@MSSM.EDU

Submission Number: 17144

IRB Number: IRB00000204

#### 4. Information on Each IRB to be Registered, Updated, or Renewed

##### Mount Sinai School of Medicine IRB #1 - Board B

1) Has the IRB or its parent organization been accredited by a human subject protection accrediting organization?

If yes, provide the name of the accrediting organization:  
and the date of accreditation:

2) Approximate total number of currently active protocols: LARGE (100+)

3) Approximate number of full time positions devoted to this IRB's administrative activities: 10

4) Does the IRB review, or intend to review, research supported by the US Govt? YES

5) Approximate number of currently active protocols supported by HHS: LARGE (100+)

6) Approximate number of currently active protocols supported by other Federal Agencies: LARGE (100+)

7) Does the IRB review, or intend to review, FDA-regulated research? YES

8) Approximate number of currently active protocols involving FDA-regulated products: LARGE (100+)

9) Currently active FDA-regulated protocols involve:

HUMAN DRUGS

MEDICAL DEVICES

BIOLOGICAL PRODUCTS

OTHER

#### 5. IRB Chairperson

First Name: JEFF

Middle Initial: H

Last Name: SILVERSTEIN

Degrees or Suffix: M.D.

Organizational Title: CHAIRPERSON, IRB/ASSOC.DEAN FOR RESEARCH

Organization: MOUNT SINAI SCHOOL OF MEDICINE

Telephone:

Fax:

E-Mail: JEFF.SILVERSTEIN@MSSM.EDU

Mailing Address: ONE GUSTAVE L. LEVY PLACE

BOX 1075

Street Address:

City: NEW YORK

State: NY

Zip Code: 10029

Submission Number: 17144

IRB Number: IRB00000204

## MOUNT SINAI SCHOOL OF MEDICINE IRB #1 - BOARD B MEMBER ROSTER

## VOTING MEMBERS

| Mem # | Name  | Gender | Affiliated? | Scientist? | Degree | Specialty                                |
|-------|---|--------|-------------|------------|--------|--|
| 1     | (Chair) SILVERSTEIN, JEFFREY<br>Comment: Fischer, Scher (Anesth); any scientific member on any board (to maintain quorum) | M      | Y           | Y          | M.D.   | Anesthesia                               |
| 13    | PACIUCCI, PAOLO<br>Comment: alternate for Gabrilove, Grosskreutz, Sung, Lipsey, Grunwald                                  | M      | Y           | Y          | MD     | Medical Oncology                         |
| 16    | STERN, ERIC<br>Comment: alternate for DiLuozzo  | M      | Y           | Y          | MD     | Medicine, Cardiology                     |
| 34    | STARR, JAY<br>Comment: alternate for nonscientific members of any board   | M      | N           | N          | JD     | Business                                 |
| 37    | MITROPOULOU, VIVIAN<br>Comment: alt for Gagliardi, Wilets   | F      | Y           | Y          | MA     | psychiatry, research design              |
| 38    | KOSTAKOGLU, LALE<br>Comment: alternate for Prohovnik  | F      | Y           | Y          | M.D.   | Radiology                                |
| 39    | SINGH, GOBIND   | M      | Y           | Y          | BA     | medical and PhD student                  |
| 43    | ALTMAN, KEN   | F      | Y           | Y          | MD     | Otolaryngology                           |
| 44    | AMES, SCOTT<br>Comment: alternate for DeBoccardo  | M      | Y           | Y          | MD     | Transplant, Surgery, Kidney, Pancreas, P |
| 45    | FARKOUH, MICHAEL<br>Comment: alternate for Stern, Godfrey, Sacks, DiLuozzo  | M      | Y           | Y          | MD     | Cardiology, Epidemiology                 |
| 48    | POPOVSKY, MARK<br>Comment: alternate for nonscientific members of any board   | M      | N           | N          | BA     | bioethics                                |
| 49    | MORLAND, KIMBERLY<br>Comment: alt for Butts Sacks Weissman Wilets Golden Westheimer Gagliardi                             | F      | Y           | Y          | PhD    | Epidemiology, Public Health              |
| 51    | COHEN, IVY<br>Comment: alternate for Meyer  | F      | Y           | Y          | BS     | Pharmacy                                 |
| 52    | WEINTRAUB, ANDREA<br>Comment: alternate for Butts, Lee  | F      | Y           | Y          | MD     | Pediatrics, Neonatology                  |
| 53    | WESTHEIMER, EMILY<br>Comment: Mitropoulou; for epid: MorlandWiletsNassissiRojasButtsWeissmanGoldenGagliardi               | F      | Y           | Y          | MS     | Epidemiology                             |

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IRB Number: IRB00000204

## MOUNT SINAI SCHOOL OF MEDICINE IRB #1 - BOARD B MEMBER ROSTER

## ALTERNATE MEMBERS

| Alt # | Name  | Gender | Affiliated? | Scientist? | Degree | Specialty                 |
|-------|---|--------|-------------|------------|--------|---------------------------|
| 36    | BIENSTOCK, CAROL<br>Substitutes: alternate for nonscientific members of any board | F      | Y           | N          | BA     | IRB Administration        |
| 47    | CARUSO, SUZANNE<br>Substitutes: alternate for nonscientific members of any board  | F      | Y           | N          | BS     | human research protection |



Submission Number: 17144

IRB Number: IRB00004094

## MOUNT SINAI SCHOOL OF MEDICINE IRB #2 - EXECUTIVE IRB MEMBER ROSTER

## VOTING MEMBERS

| Mem # | Name                                 | Gender | Affiliated? | Scientist? | Degree | Specialty           |
|-------|--------------------------------------|--------|-------------|------------|--------|---------------------|
| 1     | (Chair) SILVERSTEIN, JEFFREY         | M      | Y           | Y          | MD     | Anesthesiology      |
| 2     | MARTIN, GLENN<br>Comment: Vice-Chair | M      | Y           | Y          | MD     | Psychiatry          |
| 3     | BIENSTOCK, CAROL                     | F      | Y           | N          | BA     | IRB Administration  |
| 5     | MCNAMARA, NAN                        | F      | N           | N          | MA     | Law                 |
| 6     | STERN, ERIC                          | M      | Y           | Y          | MD     | Cardiology          |
| 7     | WILETS, ILENE                        | F      | Y           | Y          | PhD    | Emergency Med; GCRC |

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## MOUNT SINAI SCHOOL OF MEDICINE IRB #2 - EXECUTIVE IRB MEMBER ROSTER

## ALTERNATE MEMBERS

| Alt # | Name  | Gender | Affiliated? | Scientist? | Degree | Specialty                         |
|-------|---|--------|-------------|------------|--------|-----------------------------------|
| 8     | EISENMAN, JOSEPH<br>Substitutes: 3,5,7                            | M      | Y           | Y          | PhD    | Physiology/Biophysics             |
| 9     | FRANK, BEA<br>Substitutes: 3,5,7                                  | F      | Y           | N          | JD     | Law                               |
| 10    | SUNG, MAX<br>Substitutes: 1,2,4,6,7                               | M      | Y           | Y          | MD     | Gene Therapy, Molec Med, Oncology |
| 11    | JENNEX, LORI<br>Substitutes: alternate for Bienstock, McNamara    | F      | Y           | N          | MA     | human subject protection          |
| 12    | CARUSO, SUZANNE<br>Substitutes: alternate for McNamara, Bienstock | F      | Y           | N          | BA     | human subject protection          |



Submission Number: 17144

IRB Number: IRB00005471

## MOUNT SINAI SCHOOL OF MEDICINE IRB #3 - BOARD A MEMBER ROSTER

## VOTING MEMBERS

| Mem # | Name   | Gender | Affiliated? | Scientist? | Degree   | Specialty                                |
|-------|--|--------|-------------|------------|----------|--|
| 1     | (Chair) MARTIN, GLENN<br>Comment: alt for New, Ernst; scientific member on any board to maintain quorum, chair mtg | M      | Y           | Y          | MD       | Psychiatry, Medical Informatics, HIPAA   |
| 2     | BUTTS, GARY<br>Comment: alternate for Weintraub; epid/CM: Westheimer, Morland, Wilets, Nassissi, Golden            | M      | Y           | Y          | MD       | Pediatrics, Community Medicine           |
| 5     | FISCHER, GREGORY<br>Comment: alternate for Silverstein, Scher  | F      | Y           | Y          | MD       | Anesthesiology                           |
| 9     | THOMAS, NANCY<br>Comment: alternate for nonscientific members of any board   | F      | Y           | N          | BS       | clinical research management             |
| 10    | REICH, LAWRENCE<br>Comment: alternate for Nassissi   | M      | Y           | Y          | MD, Ph.D | Internal Medicine, Primary Care          |
| 11    | SACKS, HENRY<br>Comment: ButtsMorlandWeissmanWilets; epid/CM WestheimerMitropoulouNassissiGoldenGagliardi          | M      | Y           | Y          | MD, PhD  | Community Medicine                       |
| 12    | SIMPSON, DAVID<br>Comment: alternate for Nassissi  | M      | Y           | Y          | MD       | Neurology                                |
| 14    | BRILL, JANE<br>Comment: alternate for nonscientific members of any board   | F      | N           | N          | MS       | educational counseling                   |
| 15    | MEYER, JOANNE<br>Comment: alternate for Cohen  | F      | Y           | Y          | DGcp, MS | Pharmacy                                 |
| 16    | PROHOVNIK, ISAK<br>Comment: Martin, New, Kostagolu (non-medical issues)  | F      | Y           | Y          | Ph.D.    | psychiatry and radiology                 |
| 17    | GRUNWALD, HANS<br>Comment: alternate for Gabrilove, Grosskreutz, Lipsey, Paciucci, Sung                            | M      | Y           | Y          | MD       | Oncology, internal medicine              |
| 19    | LIPSEY, LEWIS<br>Comment: alternate for Gabrilove, Grosskreutz, Grunwald, Paciucci, Sung                           | M      | Y           | Y          | MD       | hematology oncology                      |
| 20    | LEE, MEN-JEAN<br>Comment: alternate for Weintraub  | F      | Y           | Y          | MD       | Obstetrics, Gynecology, Reproductive     |
| 21    | GOLDEN, ANNE<br>Comment: alt for Gagliardi Wilets Nassissi Rojas Butts Weismann Sacks                              | F      | Y           | Y          | PhD      | Epidemiology, Biostatistics, research me |

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## MOUNT SINAI SCHOOL OF MEDICINE IRB #3 - BOARD A MEMBER ROSTER

## ALTERNATE MEMBERS

| Alt # | Name  | Gender | Affiliated? | Scientist? | Degree | Specialty                                |
|-------|---|--------|-------------|------------|--------|--|
| 8     | BIENSTOCK, CAROL<br>Substitutes: alternate for nonscientific members of any board | F      | Y           | N          | BA     | Human Subject Protection, Clinical Resea |
| 18    | JENNEX, LORI<br>Substitutes: alternate for nonscientific members of any board     | F      | Y           | N          | MA     | human research protection                |



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## MOUNT SINAI SCHOOL OF MEDICINE IRB #4 - BOARD C MEMBER ROSTER

## VOTING MEMBERS

| Mem # | Name   | Gender | Affiliated? | Scientist? | Degree   | Specialty                       |
|-------|--|--------|-------------|------------|----------|---------------------------------|
| 1     | (Chair) SILVERSTEIN, JEFF<br>Comment: alt for Fischer,Scher, scientific member any board to maintain quorum, chair mtg | M      | Y           | Y          | MD       | Anesthesiology, Gerontology     |
| 4     | DEBOCCARDO, GRACIELA<br>Comment: alternate for Ames  | F      | Y           | Y          | MD       | Int Med, Nephrology, Transplant |
| 5     | FRANK, BEATRICE<br>Comment: alternate for nonscientific members of any board   | F      | N           | N          | JD       | Law                             |
| 6     | GABRILOVE, JANICE<br>Comment: alternate for Grosskreutz, Paciucci, Sung, Grunwald, Lipsey                              | F      | Y           | Y          | MD       | Hematology, Oncology            |
| 8     | NASSISSI, DENISE<br>Comment: alternate for Reich, Simpson, Wilets  | F      | Y           | Y          | MD       | Emergency Medicine              |
| 9     | VEZINA, MARIA<br>Comment: alternate for McEvoy, Reineke  | F      | Y           | Y          | MA, EdD  | Nursing Education               |
| 10    | WEISSMAN, ANDREW<br>Comment: alternate for Butts, Morland, Sacks, Wilets   | M      | Y           | Y          | PhD      | Community Medicine              |
| 11    | MARTIN, GLENN<br>Comment: alternate for Chairs: Silverstein, Wilets  | M      | Y           | Y          | MD       | Psychiatry                      |
| 12    | MCNAMARA, NAN<br>Comment: alternate for nonscientific members of any board   | F      | N           | N          | MA       | Law                             |
| 13    | MEYER, JOANNE<br>Comment: alt for Cohen  | F      | Y           | Y          | DGcp, MS | Pharmacy                        |
| 15    | ULLMAN, THOMAS<br>Comment: alternate for Itzkowitz   | M      | Y           | Y          | MD       | Gastroenterology                |
| 16    | BERSHAD, SUSAN<br>Comment: alt for Emanuel   | F      | Y           | Y          | MD       | Dermatology                     |
| 17    | ERNST, CARRIE<br>Comment: can serve as alternate for Martin, New   | F      | Y           | Y          | MD       | psychiatry                      |
| 18    | GAGLIARDI, ROSEMARIE<br>Comment: alt for Mitropoulou, Wilets, Golden, Westheimer, Rojas, Butts (epi); Weissman         | F      | Y           | Y          | MPH, EdD | Liver Transplant                |
| 20    | REINEKE, PATRICIA R.<br>Comment: alternate for McEvoy, Vezina  | F      | Y           | Y          | PhD, RN  | Nursing                         |

Submission Number: 17144

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## MOUNT SINAI SCHOOL OF MEDICINE IRB #4 - BOARD C MEMBER ROSTER

## ALTERNATE MEMBERS

| Alt # | Name  | Gender | Affiliated? | Scientist? | Degree | Specialty                                |
|-------|---|--------|-------------|------------|--------|--|
| 14    | BIENSTOCK, CAROL<br>Substitutes: alternate for nonscientific members of any board | F      | Y           | N          | BA     | Human Research Protection, Clinical Rese |
| 19    | JENNEX, LORI<br>Substitutes: alternate for nonscientific members of any board     | F      | Y           | N          | MA     | human research protection                |

Submission Number: 17144

IRB Number: IRB00005473

#### 4. Information on Each IRB to be Registered, Updated, or Renewed

##### Mount Sinai School of Medicine IRB #5 - Board D

1) Has the IRB or its parent organization been accredited by a human subject protection accrediting organization?

If yes, provide the name of the accrediting organization:

and the date of accreditation:

2) Approximate total number of currently active protocols: LARGE (100+)

3) Approximate number of full time positions devoted to this IRB's administrative activities: 10

4) Does the IRB review, or intend to review, research supported by the US Govt? YES

5) Approximate number of currently active protocols supported by HHS: LARGE (100+)

6) Approximate number of currently active protocols supported by other Federal Agencies: LARGE (100+)

7) Does the IRB review, or intend to review, FDA-regulated research? YES

8) Approximate number of currently active protocols involving FDA-regulated products:

9) Currently active FDA-regulated protocols involve:

HUMAN DRUGS

MEDICAL DEVICES

BIOLOGICAL PRODUCTS

OTHER

#### 5. IRB Chairperson

First Name: ILENE

Middle Initial:

Last Name: WILETS

Degrees or Suffix: PHD

Organizational Title: IRB CHAIRPERSON

Organization: MOUNT SINAI SCHOOL OF MEDICINE

Telephone: 212 659-8980

Fax:

E-Mail: ILENE.WILETS@MSSM.EDU

Mailing Address: IRB, 1 GUSTAVE L LEVY PLACE BOX 1075

Street Address:

City: NEW YORK

State: NY

Zip Code: 10029

Submission Number: 17144

IRB Number: IRB00005473

## MOUNT SINAI SCHOOL OF MEDICINE IRB #5 - BOARD D MEMBER ROSTER

## VOTING MEMBERS

| Mem # | Name  | Gender | Affiliated? | Scientist? | Degree | Specialty                                |
|-------|---|--------|-------------|------------|--------|--|
| 1     | (Chair) WILETS, ILENE<br>Comment: Morland,Mitropoulou, scientif member of any board to maintain quorum, chair mtg | F      | Y           | Y          | PhD    | Emergency Medicine, GCRC Advocate        |
| 4     | GROSSKREUTZ, CELIA<br>Comment: alternate for Gabrilove, Lipsey, Paciucci, Sung                                    | F      | Y           | Y          | MD     | Hematology, Oncology                     |
| 6     | ITZKOWITZ, STEVEN<br>Comment: alternate for Ullman  | M      | Y           | Y          | MD     | Gastroenterology                         |
| 8     | MITROPOULOU, VIVIAN<br>Comment: alternate for Wilets, Gagliardi   | F      | Y           | Y          | MA     | Psychiatry                               |
| 9     | PODOS, STEVEN   | M      | Y           | Y          | MD     | Ophthalmology                            |
| 12    | SUNG, MAX<br>Comment: alternate for Gabrilove, Grosskreutz, Lipsey, Paciucci                                      | M      | Y           | Y          | MD     | Gene Therapy, Molecular Medicine, Oncolo |
| 16    | ROJAS, MARY<br>Comment: alt for Morland Sacks Weissman WestheimerNassissiWiletsButtsMitropoulouGolden             | F      | Y           | Y          | Ph.D.  | Adolescent Health, Psychiatry, Health Po |
| 17    | NEW, ANTONIA<br>Comment: alternate for Martin,Mitropoulou   | F      | Y           | Y          | MD     | Psychiatry                               |
| 18    | MCEVOY, MARY<br>Comment: alternate for Vezina, Reineke  | F      | Y           | Y          | RN     | Nursing, Oncology                        |
| 19    | DERMAN, KAYE<br>Comment: alternate for nonscientific members of any board   | F      | Y           | N          | N/A    | volunteer services                       |
| 20    | FRIERSON, SARAH<br>Comment: alternate for nonscientific members of any board                                      | F      | N           | N          | N/A    | non-scientific                           |
| 23    | DILUOZZO, GABRIELE<br>Comment: alternate for Stern, Farkouh   | F      | Y           | Y          | MD     | Cardiothoracic surgery, general surgery  |
| 24    | COHEN, IVY<br>Comment: alternate for Meyer  | F      | Y           | N          | BS     | Pharmacy                                 |
| 25    | EMANUEL, PATRICK<br>Comment: alt for Bershad  | M      | Y           | Y          | MD     | Dermatology/Pathology                    |
| 26    | SCHER, COREY<br>Comment: alternate for Fischer, Silverstein   | M      | Y           | Y          | M.D.   | Anesthesiology, Pediatrics               |

Submission Number: 17144

IRB Number: IRB00005473

## MOUNT SINAI SCHOOL OF MEDICINE IRB #5 - BOARD D MEMBER ROSTER

## ALTERNATE MEMBERS

| Alt # | Name  | Gender | Affiliated? | Scientist? | Degree | Specialty                                |
|-------|---|--------|-------------|------------|--------|--|
| 15    | BIENSTOCK, CAROL<br>Substitutes: alternate for nonscientific members of any board | F      | Y           | N          | BA     | Human Research Protection, Clinical Rese |
| 22    | CARUSO, SUZANNE<br>Substitutes: alternate for nonscientific members of any board  | F      | Y           | N          | BA     | human research protection                |

Public burden for this collection of information is estimated to average one hour for an initial IRB registration or a complete update of an existing IRB registration and 30 minutes for a limited update of an IRB registration. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: OS Reports Clearance Officer, Room 503, 200 Independence Avenue, SW., Washington, DC 20201. Do not return the completed form to this address.