

Submission#: 22298
IORG#: IORG0000124
Institution: Mount Sinai School of Medicine

OMB No. 0990-0279
Approved for use June 30, 2012

U.S. Department of Health and Human Services (HHS) Registration of an Institutional Review Board (IRB)

This form is used by institutions or organizations operating IRBs that review:

- a) Research involving human subjects conducted or supported by the Department of Health and Human Services, or other federal departments or agencies that apply the Federal Policy for the Protection of Human Subjects to such research; and/or**
- b) Clinical investigations regulated by the Food and Drug Administration (FDA) of the Department of Health and Human Services**

This form is used by institutions or organizations operating IRBs that review:

- a. To register an IRB if your institution or organization has not previously registered an IRB
- b. To update or renew the registration of an IRB previously registered by your institution or organization
- c. To add another IRB to those previously registered by your institution or organization

Fields with an * are required for OHRP IRBs and FDA IRBs

Fields with an ♦ are required for OHRP IRBs but are optional for FDA IRBs

Fields with an ‡ are required for FDA IRBs but are optional for OHRP IRBs

Fields with no symbol are optional for both OHRP IRBs and FDA IRBs

1. *Has your institution or organization previously registered an IRB with the Office for Human Research Protections (OHRP)?

Yes, proceed to section 2 No, proceed to section 3

2. *What is your institution or organization (IORG) number? IORG0000124

This number was provided by OHRP the first time your institution or organization registered an IRB. If you do not know your IORG number, search for your institution or organization on the OHRP website at <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR> or contact OHRP using the contact information at <http://www.hhs.gov/ohrp/daqi-staff.html> or by telephone at 1-866-447-4777.

3. Name of Institution or Organization Operating the IRB(s)

*Name of Institution or Organization: Mount Sinai School of Medicine

*Mailing Address: **One Gustave L. Levy Place Box 1075**

*Street Address (if different from the Mailing Address above):

3 East 101st, First Floor, New York, NY 10029

*City: **New York**

*State/Province **NY**

*Zip/Postal Code: **10029-6754**

*Country (if outside the U.S.):

4. Senior Officer or Head Official of Institution or Organization Responsible for Overseeing the Activities Performed by the IRB(s)

*First Name: **Dennis**

Middle Initial: **S** *Last Name: **Charney**

Earned Degree(s): **M.D.**

Title or Position: **Dean, MSSM; Exec VP**

*Mailing Address (if different from the Mailing Address in section 3):

One Gustave Levy Place Box 1217

ATTENTION: IRB

*City: **New York**

*State/Province **NY**

*Zip/Postal Code: **10029**

*Country (if outside the U.S.):

*Phone: **212 241-5674**

*FAX: **212 824-2302**

*E-Mail: **dennis.charney@mssm.edu**

5. Contact Person Providing this Registration Information

*First Name: **Carol**

Middle Initial: *Last Name: **Bienstock**

Earned Degree(s): **CIP, CCRC**

Title or Position: **Director of Regulator**

Name of Institution or Organization (if different from the Name in section 3):

Mount Sinai School of Medicine

*Mailing Address (if different from the Mailing Address in section 3):

One Gustave L. Levy Place Box 1075

*City: **New York**

*State/Province **NY**

*Zip/Postal Code: **10029-6754**

*Country (if outside the U.S.):

*Phone: **212 659-8980**

*FAX: **212 876-6789**

*E-Mail: **Carol.Bienstock@mssm.edu**

6. IRB Registration Information (to be completed separately for each IRB being renewed/updated or newly registered)

A. *Is this a renewal or update of a registration for an IRB already registered with HHS?

Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: **IORG0000124**

(This number was provided by OHRP the first time the IRB was registered with OHRP. If you do not know

the IRB registration number, search for the IRB on the OHRP website at <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR> or contact OHRP using the contact information at <http://www.hhs.gov/ohrp/daqi-staff.html> or by telephone at 1-866-447-4777)

No, this is a new IRB registration.

B. Provide the IRB name, if any, used by the institution or organization (e.g., State University Behavioral IRB, University Healthcare Biomedical IRB, or XYZ Hospital IRB #1):

Mount Sinai School of Medicine IRB #1 - Board B

C. Location of the IRB **24026**

*Mailing Address (if different from the Mailing Address in section 3):

One Gustave L. Levy Place Box 1075

*Street Address of the IRB (if different from the Mailing Address of the IRB):

1425 Madison Avenue, Icahn Building Suite 4-78

*City: **New York**

*State/Province **NY**

*Zip/Postal Code: **10029-6754**

*Country (if outside the U.S.):

*Phone: **212 659-8980**

*FAX: **212 876-6789**

*E-Mail: **carol.bienstock@mssm.edu**

D. ♦Approximate number of full time equivalent positions devoted to the IRB's administrative activities: **17**

E. ♦Approximate number of all active protocols (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months): **1800**

F. ♦Approximate number of active protocols conducted or supported by HHS (e.g., the National Institutes of Health, Centers for Disease Control and Prevention, etc.) (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months): **150**

G. ‡For IRBs that review, or intend to review, protocols involving products regulated by the Food and Drug Administration (FDA) (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months):

‡i) Approximate number of active protocols involving FDA-regulated products: **360**

‡ii) Types of FDA-regulated products involved in FDA protocols include (check all that apply):

<input checked="" type="checkbox"/> human drugs	food additives
<input checked="" type="checkbox"/> medical devices	color additives
<input checked="" type="checkbox"/> biological products	other

Specify:

H. IRB Chairperson

*First Name: **Jeff** Middle Initial: *Last Name: **Silverstein**
Earned Degree(s): **M.D.** Title or Position: **Chairperson, IRB/Assoc. Dean for Research**

*Mailing Address (if different from the Mailing Address in section 3):

**One Gustave L. Levy Place
Box 1075**

*City: **New York** *State/Province **NY** *Zip/Postal Code: **10029**

*Country (if outside the U.S.):

*Phone: **212 659-8980** *FAX: *E-Mail: **Jeff.Silverstein@mssm.edu**

I. ♦IRB Roster Form: Completion of the IRB Roster Form is required if your IRB is designated on a Federalwide assurance submitted to OHRP. Otherwise, it is optional.

Member Name (Last, First)	Sex M/F	Earned Degree(s)	Scientist (S) or Non-scientist (N)	Primary Scientific or Non-Scientific Specialty	Affiliation with Institution(s) Y/N	Comments
Silverstein, Jeff	M	M.D.	Y	Anesthesia	Y	Fischer (Anesth); any scientific member on any board (to maintain quorum)
Stern, Eric	M	MD	Y	Medicine, Cardiology	Y	Alt for Garcia
Starr, Jay	M	JD	N	Business	N	alternate for nonscientific members of any board
Mitropoulou, Vivian	F	MA	Y	psychiatry, research design	Y	alt for Wilets, psych - Cantor
Benor, Miriam	F	JD	N	Psychology/Law	N	alternate for nonscientific members of any board
Altman, Ken	F	MD	Y	Otolaryngology	Y	Alt for Sikora, Malkin
Farkouh, Michael	M	MD	Y	Cardiology, Epidemiology	Y	alternate for Sacks, Stern, cardio: Garcia
Hulkower, Adira	F	JD	N	Non-Scientific	N	alternate for nonscientific members of any board
Chikwe, Joanna	F	MD	Y	Cardiothoracic surgery	Y	
Friedman, Alan	M	MD	Y	Ophthalmology	Y	Alt for Forooghian
Cohen, Ivy	F	BS	Y	Pharmacy	Y	alternate for Meyer
Weintraub, Andrea	F	MD	Y	Pediatrics, Neonatology	Y	alternate for Lee
Delman, Bradley	F	MD	Y	Radiology	Y	Alt for Prohovnik, Kao
Sehba, Fatima	M	Ph.D.	Y	Neurosurgery	Y	Alt for Choudhri
Tosi, Michael	M	MD	Y	Pediatrics, Infectious Diseases	Y	Rojas, Weintraub, Factor
Garcia, Mario	M	MD	Y	Cardiology	Y	Alt for Stern, Farkouh
Soorya, Latha	F	Ph.D.	Y	Psychiatry	Y	Alt for Ernst, Martin
Kerr, Leslie	F	MD	Y	Internal Medicine, Rheumatology	Y	Alt Reich,Schlondorff,Sachar,Klein, Kalb, Stulman,Malone,Adelson,Thoma
Matos, Patricia	F	DNP, RN	Y	Nursing, Psychiatry	Y	Alt for Vezina
Klein, Robert	M	MD	Y	Internal Medicine, Infectious Diseases	Y	Alt Reich,Schlondorff,Sachar,Kalb, Stulman,Malone,Adelson,Tosi, Factor
DeAngelis, Teresa	F	MD	Y	Neurology	Y	Alt for Demopoulous, Levine

Alternative Members

Banchik, Rebecca		F	BA	IRB Administration	Y	alternate for nonscientific members of any board
Bienstock, Carol		F	BA	IRB Administration	Y	alternate for nonscientific members of any board

NOTES:

Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.

Affiliation: Please indicate whether or not each individual (or a member of that person's immediate family) is affiliated (other than as an IRB member) with the institution or organization operating the IRB.

Yes = The IRB member is affiliated with the institution or organization operating the IRB.

No = The individual is not affiliated with the institution or organization operating the IRB.

Alternate Members: An alternate member(s) may be designated, as needed, for a regular voting member(s). An alternate member may vote only when the regular voting member is not voting.

When an institution or organization registers two or more IRBs, all alternate members for all IRBs may be listed on the roster of one IRB, or they may be listed separately with each IRB roster. A primary member of any IRB registered under the same IORG number may serve as an alternate for any comparably qualified member on any other IRB of that institution or organization. Primary members on registered IRBs serving as alternate members do not need to be listed as an alternate on any roster. Each alternate IRB member who replaces a primary member at any given meeting should have experience, expertise, background, professional competence, and knowledge equivalent to that of the primary IRB member whom the alternate will replace. Whenever an alternate member substitutes for a primary member of the IRB, the combined requirements of § 46.107(a) and 46.108(b) shall remain satisfied. Whenever this occurs, the minutes of the IRB meeting should indicate clearly that the alternate IRB member has replaced the designated primary IRB member, and include the identity of the replaced primary and the alternate members. If multiple alternate members serve at an IRB meeting, the pairing of primary and alternate members should be indicated.

A. *Is this a renewal or update of a registration for an IRB already registered with HHS?

Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: **IORG0000124**

(This number was provided by OHRP the first time the IRB was registered with OHRP. If you do not know

the IRB registration number, search for the IRB on the OHRP website at <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR> or contact OHRP using the contact information at <http://www.hhs.gov/ohrp/daqi-staff.html> or by telephone at 1-866-447-4777)

No, this is a new IRB registration.

B. Provide the IRB name, if any, used by the institution or organization (e.g., State University Behavioral IRB, University Healthcare Biomedical IRB, or XYZ Hospital IRB #1):

Mount Sinai School of Medicine IRB #2 - Executive IRB

C. Location of the IRB **24027**

*Mailing Address (if different from the Mailing Address in section 3):

One Gustave L. Levy Place Box 1075

*Street Address of the IRB (if different from the Mailing Address of the IRB):

1425 Madison Avenue, Icahn Building Suite 4-78

*City: **New York**

*State/Province **NY**

*Zip/Postal Code: **10029-6754**

*Country (if outside the U.S.):

*Phone: **212 659-8980**

*FAX: **212 876-6789**

*E-Mail: **carol.bienstock@mssm.edu**

D. ♦Approximate number of full time equivalent positions devoted to the IRB's administrative activities: **17**

E. ♦Approximate number of all active protocols (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months): **1800**

F. ♦Approximate number of active protocols conducted or supported by HHS (e.g., the National Institutes of Health, Centers for Disease Control and Prevention, etc.) (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months): **150**

G. ‡For IRBs that review, or intend to review, protocols involving products regulated by the Food and Drug Administration (FDA) (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months):

‡i) Approximate number of active protocols involving FDA-regulated products: **360**

‡ii) Types of FDA-regulated products involved in FDA protocols include (check all that apply):

<input checked="" type="checkbox"/> human drugs	food additives
<input checked="" type="checkbox"/> medical devices	color additives
<input checked="" type="checkbox"/> biological products	other

Specify:

H. IRB Chairperson

*First Name: **Jeff** Middle Initial: **H** *Last Name: **Silverstein**
Earned Degree(s): **MD** Title or Position: **Chairperson, IRB/Assoc. Dean for Research**
*Mailing Address (if different from the Mailing Address in section 3):
1 Gustave L. Levy Place Box 1075
*City: **New York** *State/Province **NY** *Zip/Postal Code: **10029**
*Country (if outside the U.S.):
*Phone: **212 659-8980** *FAX: **212 876-6789** *E-Mail: **jeff.silverstein@mssm.edu**

I. ♦IRB Roster Form: Completion of the IRB Roster Form is required if your IRB is designated on a Federalwide assurance submitted to OHRP. Otherwise, it is optional.

Member Name (Last, First)	Sex M/F	Earned Degree(s)	Scientist (S) or Non-scientist (N)	Primary Scientific or Non-Scientific Specialty	Affiliation with Institution(s) Y/N	Comments
Silverstein, Jeffrey	M	MD	Y	Anesthesiology	Y	
Martin, Glenn	M	MD	Y	Psychiatry	Y	Vice-Chair
Bienstock, Carol	F	BA	N	IRB Administration	Y	
McNamara, Nan	F	MA	N	Law	N	
Stern, Eric	M	MD	Y	Cardiology	Y	
Wilets, Ilene	F	PhD	Y	Emergency Med; GCRC	Y	

Alternative Members

Frank, Bea		F	JD	Law	Y	3,5,7
Jennex, Lori		F	MA	human subject protection	Y	alternate for Bienstock, McNamara
Sung, Max		M	MD	Gene Therapy, Molec Med, Oncology	Y	1,2,4,6,7
Eisenman, Joseph		M	PhD	Physiology/Biophysics	Y	3,5,7
Banchik, Rebecca		F	BA	human subject protection	Y	alternate for Bienstock, McNamara

NOTES:

Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.

Affiliation: Please indicate whether or not each individual (or a member of that person's immediate family) is affiliated (other than as an IRB member) with the institution or organization operating the IRB.

Yes = The IRB member is affiliated with the institution or organization operating the IRB.

No = The individual is not affiliated with the institution or organization operating the IRB.

Alternate Members: An alternate member(s) may be designated, as needed, for a regular voting member(s). An alternate member may vote only when the regular voting member is not voting.

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A. *Is this a renewal or update of a registration for an IRB already registered with HHS?

Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: **IORG0000124**

(This number was provided by OHRP the first time the IRB was registered with OHRP. If you do not know

the IRB registration number, search for the IRB on the OHRP website at <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR> or contact OHRP using the contact information at <http://www.hhs.gov/ohrp/daq-staff.html> or by telephone at 1-866-447-4777)

No, this is a new IRB registration.

B. Provide the IRB name, if any, used by the institution or organization (e.g., State University Behavioral IRB, University Healthcare Biomedical IRB, or XYZ Hospital IRB #1):

Mount Sinai School of Medicine IRB #3 - Board A

C. Location of the IRB **24028**

*Mailing Address (if different from the Mailing Address in section 3):

One Gustave L. Levy Place Box 1075

*Street Address of the IRB (if different from the Mailing Address of the IRB):

3 East 101st, First Floor, New York, NY 10029

*City: **New York**

*State/Province **NY**

*Zip/Postal Code: **10029-6754**

*Country (if outside the U.S.):

*Phone: **212 659-8974**

*FAX: **212 867-6789**

*E-Mail: **carol.bienstock@mssm.edu**

D. ♦Approximate number of full time equivalent positions devoted to the IRB's administrative activities: **17**

E. ♦Approximate number of all active protocols (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months): **1800**

F. ♦Approximate number of active protocols conducted or supported by HHS (e.g., the National Institutes of Health, Centers for Disease Control and Prevention, etc.) (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months): **150**

G. ‡For IRBs that review, or intend to review, protocols involving products regulated by the Food and Drug Administration (FDA) (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months):

‡i) Approximate number of active protocols involving FDA-regulated products: **360**

‡ii) Types of FDA-regulated products involved in FDA protocols include (check all that apply):

<input checked="" type="checkbox"/> human drugs	food additives
<input checked="" type="checkbox"/> medical devices	color additives
<input checked="" type="checkbox"/> biological products	other

Specify:

H. IRB Chairperson

*First Name: **Glenn** Middle Initial: *Last Name: **Martin**

Earned Degree(s): **MD** Title or Position: **IRB Chairperson**

*Mailing Address (if different from the Mailing Address in section 3):

Institutional Review Board 1 Gustave L Levy Box 1075

*City: **New York** *State/Province **NY** *Zip/Postal Code: **10029**

*Country (if outside the U.S.):

*Phone: **212 659-8980** *FAX: *E-Mail: **glenn.martin@mssm.edu**

I. ♦IRB Roster Form: Completion of the IRB Roster Form is required if your IRB is designated on a Federalwide assurance submitted to OHRP. Otherwise, it is optional.

Member Name (Last, First)	Sex M/F	Earned Degree(s)	Scientist (S) or Non-scientist (N)	Primary Scientific or Non-Scientific Specialty	Affiliation with Institution(s) Y/N	Comments
Martin, Glenn	M	MD	Y	Psychiatry, Medical Informatics, HIPAA	Y	alt for Ernst; scientific member on any board to maintain quorum, chair mtg
Fischer, Gregory	F	MD	Y	Anesthesiology	Y	alt for Silverstein, Vouyouka
Thomas, Nancy	F	BS	N	clinical research management	Y	alternate for nonscientific members of any board
Reich, Lawrence	M	MD, Ph.D	Y	Internal Medicine, Primary Care	Y	alt Nasissi,Kerr,Klein,Kalb, Thomas,Adelson,Malone, Schlondorff,Sachar
Sacks, Henry	M	MD, PhD	Y	Community Medicine	Y	Alt Weissman,Wilets,Factor; epid/CM Mitropoulou,Nasissi,Golden, Factor
Brill, Jane	F	MS	N	educational counseling	N	alternate for nonscientific members of any board
Meyer, Joanne	F	DGcp, MS	Y	Pharmacy	Y	alternate for Cohen
Prohovnik, Isak	F	Ph.D.	Y	psychiatry and radiology	Y	Alt for Martin, radiology: Delman, Carpenter
Grunwald, Hans	M	MD	Y	Oncology, internal medicine	Y	alternate for Sung, Germain, Malone, Droller
Feiner, Harriet	F	LMSW	N	Social Work	N	alternate for nonscientific members of any board
Lee, Men-Jean	F	MD	Y	Obstetrics, Gynecology, Reproductive	Y	alternate for Weintraub
Golden, Anne	F	PhD	Y	Epidemiology, Biostatistics, research me	Y	alt for Wilets Nasissi Rojas Weismann Sacks
Vouyouka, Ageliki	F	MD	Y	Surgery	Y	Alt for Fischer
Demopoulos, Alexis	F	MD	Y	Neurology, Neuro-oncology	Y	Alt for DeAngelis, Levine
Malkin, Benjamin	M	AB, MD	Y	Otolaryngology	Y	Alt for Sikora, Altman
Sachar, David	M	MD	Y	Internal Medicine, Gastroenterology	Y	Alt for Schlondorff, Kerr, Klein, Kalb, Stulman, Malone, Reich, Adel
Schlondorff, Detlef	M	MD	Y	Internal Medicine, Nephrology	Y	Alt Sachar, Kerr,Klein,Kalb,Stulman, Malone, Reich, Adelson, Thomas
Striker, Gary	M	MD	Y	Geriatrics, Pathology	Y	Alt for Pessin, Silverstein
Martin, Lisa	F	PhD, RN	Y	Nursing	Y	Alt for Matos, Vezina
Pessin-Minsley, Melissa	F	PhD, MD	Y	Pathology	Y	Alt for Striker
Droller, Michael	M	MD	Y	Urology	Y	Alt for Grunwald
Choudhri, Tanvir	M	MD	Y	Neurosurgery	Y	Alt for Sebha
Levine, Steven	M	M.D.	Y	Neurology	Y	DeAnglis, Choudhri, Demopoulos, Nasissi

Alternative Members

Bienstock, Carol		F	BA	Human Subject Protection, Clinical Resea	Y	alternate for nonscientific members of any board
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Jennex, Lori

F

MA

human research protection

Y

alternate for nonscientific
members of any board

NOTES:

Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.

Affiliation: Please indicate whether or not each individual (or a member of that person's immediate family) is affiliated (other than as an IRB member) with the institution or organization operating the IRB.

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A. *Is this a renewal or update of a registration for an IRB already registered with HHS?

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the IRB registration number, search for the IRB on the OHRP website at <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR> or contact OHRP using the contact information at <http://www.hhs.gov/ohrp/daqi-staff.html> or by telephone at 1-866-447-4777)

No, this is a new IRB registration.

B. Provide the IRB name, if any, used by the institution or organization (e.g., State University Behavioral IRB, University Healthcare Biomedical IRB, or XYZ Hospital IRB #1):

Mount Sinai School of Medicine IRB #4 - Board C

C. Location of the IRB **24029**

*Mailing Address (if different from the Mailing Address in section 3):

One Gustave L. Levy Place Box 1075

*Street Address of the IRB (if different from the Mailing Address of the IRB):

3 East 101st, First Floor, New York, NY 10029

*City: **New York**

*State/Province **NY**

*Zip/Postal Code: **10029-6754**

*Country (if outside the U.S.):

*Phone: **212 659-8980**

*FAX: **212 876-6789**

*E-Mail: **carol.bienstock@mssm.edu**

D. ♦Approximate number of full time equivalent positions devoted to the IRB's administrative activities: **17**

E. ♦Approximate number of all active protocols (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months): **1800**

F. ♦Approximate number of active protocols conducted or supported by HHS (e.g., the National Institutes of Health, Centers for Disease Control and Prevention, etc.) (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months): **150**

G. ‡For IRBs that review, or intend to review, protocols involving products regulated by the Food and Drug Administration (FDA) (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months):

‡i) Approximate number of active protocols involving FDA-regulated products: **360**

‡ii) Types of FDA-regulated products involved in FDA protocols include (check all that apply):

<input checked="" type="checkbox"/> human drugs	food additives
<input checked="" type="checkbox"/> medical devices	color additives
<input checked="" type="checkbox"/> biological products	other

Specify:

H. IRB Chairperson

*First Name: **Jeff** Middle Initial: *Last Name: **Silverstein**
Earned Degree(s): **MD** Title or Position: **Vice-Chair, IRB; Associate Dean for Research**
*Mailing Address (if different from the Mailing Address in section 3):
IRB, 1 Gustave L Levy Place Box 1075
*City: **New York** *State/Province **NY** *Zip/Postal Code: **10029**
*Country (if outside the U.S.):
*Phone: **212 659-8980** *FAX: *E-Mail: **jeff.silverstein@mssm.edu**

I. ♦IRB Roster Form: Completion of the IRB Roster Form is required if your IRB is designated on a Federalwide assurance submitted to OHRP. Otherwise, it is optional.

Member Name (Last, First)	Sex M/F	Earned Degree(s)	Scientist (S) or Non-scientist (N)	Primary Scientific or Non-Scientific Specialty	Affiliation with Institution(s) Y/N	Comments
Silverstein, Jeff	M	MD	Y	Anesthesiology, Gerontology	Y	alt for Fischer, scientific member any board to maintain quorum, chair mtg
Frank, Beatrice	F	JD	N	Law	N	alternate for nonscientific members of any board
Nasissi, Denise	F	MD	Y	Emergency Medicine	Y	alternate for Reich, Wilets
Vezina, Maria	F	MA, EdD	Y	Nursing Education	Y	Alt for Matos, Martin L.
Weissman, Andrew	M	PhD	Y	Community Medicine	Y	alternate for Sacks, Wilets
Martin, Glenn	M	MD	Y	Psychiatry	Y	alternate for Chairs: Silverstein, Wilets
McNamara, Nan	F	MA	N	Law	N	alternate for nonscientific members of any board
Meyer, Joanne	F	DGcp, MS	Y	Pharmacy	Y	alt for Cohen
Ullman, Thomas	M	MD	Y	Gastroenterology	Y	alternate for Itzkowitz, Odin
Bershad, Susan	F	MD	Y	Dermatology	Y	alt for Emanuel
Ernst, Carrie	F	MD	Y	psychiatry	Y	Alt for Martin, Soorya
Malone, Adriana	F	MD	Y	Internal Medicine/Medical Oncology	Y	Grun, SungGermainAdelsonKerrKlein Kalb,Thomas, StulmanReichSachar,Schlondorf
Ambrose, Ann	F	MD, MS	Y	Rehab Medicine	Y	Alt for Thomas, D, Cantor
Thomas, David	M	MD	Y	Internal Medicine, Rehab	Y	Reich, SchlondorffSacharKerrKleinKal b,StulmanMalone,Adelson, AmbroseCantor
Forooghian, Farzin	M	MD, MSc, FRCSC	Y	Ophthalmology, Immunology	Y	Alt for Friedman
Carpenter, David	M	PhD	Y	Radiology	Y	Alt for Prohovnik
Chun, Jin	M	MD	Y	Plastic Surgery	Y	Alt for Herron
Odin, Joseph	M	MD, PhD	Y	Medicine, Gastroenterology	Y	Alt for Ullman, Itzkowitz
Kao, Johnny	M	MD	Y	Radiation Oncology	Y	Delman
Adelson, Kerin	M	MD	Y	Internal Medicine, Medical Oncology	Y	Reich,Schlondorff,Sachar,Klein, Kerr,Kalb, Malone,Thomas,Stulman
Wasserstein, Melissa	F	MD	Y	Clinical Biochemical Genetics, Clinical	Y	Alt for Willner, Rojas, Weintraub
Stein, Richard	M	MD	Y	Medicine, Nephrology	Y	

Alternative Members

Bienstock, Carol		F	BA	Human Research Protection, Clinical Rese	Y	alternate for nonscientific members of any board
Jennex, Lori		F	MA	human research protection	Y	alternate for nonscientific members of any board

NOTES:

Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.

Affiliation: Please indicate whether or not each individual (or a member of that person's immediate family) is affiliated (other than as an IRB member) with the institution or organization operating the IRB.

Yes = The IRB member is affiliated with the institution or organization operating the IRB.

No = The individual is not affiliated with the institution or organization operating the IRB.

Alternate Members: An alternate member(s) may be designated, as needed, for a regular voting member(s). An alternate member may vote only when the regular voting member is not voting.

When an institution or organization registers two or more IRBs, all alternate members for all IRBs may be listed on the roster of one IRB, or they may be listed separately with each IRB roster. A primary member of any IRB registered under the same IORG number may serve as an alternate for any comparably qualified member on any other IRB of that institution or organization. Primary members on registered IRBs serving as alternate members do not need to be listed as an alternate on any roster. Each alternate IRB member who replaces a primary member at any given meeting should have experience, expertise, background, professional competence, and knowledge equivalent to that of the primary IRB member whom the alternate will replace. Whenever an alternate member substitutes for a primary member of the IRB, the combined requirements of § 46.107(a) and 46.108(b) shall remain satisfied. Whenever this occurs, the minutes of the IRB meeting should indicate clearly that the alternate IRB member has replaced the designated primary IRB member, and include the identity of the replaced primary and the alternate members. If multiple alternate members serve at an IRB meeting, the pairing of primary and alternate members should be indicated.

A. *Is this a renewal or update of a registration for an IRB already registered with HHS?

Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: **IORG0000124**

(This number was provided by OHRP the first time the IRB was registered with OHRP. If you do not know

the IRB registration number, search for the IRB on the OHRP website at <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR> or contact OHRP using the contact information at <http://www.hhs.gov/ohrp/daqi-staff.html> or by telephone at 1-866-447-4777)

No, this is a new IRB registration.

B. Provide the IRB name, if any, used by the institution or organization (e.g., State University Behavioral IRB, University Healthcare Biomedical IRB, or XYZ Hospital IRB #1):

Mount Sinai School of Medicine IRB #5 - Board D

C. Location of the IRB **24030**

*Mailing Address (if different from the Mailing Address in section 3):

One Gustave L. Levy Place Box 1075

*Street Address of the IRB (if different from the Mailing Address of the IRB):

3 East 101st, First Floor, New York, NY 10029

*City: **New York**

*State/Province **NY**

*Zip/Postal Code: **10029-6754**

*Country (if outside the U.S.):

*Phone: **212 659-8980**

*FAX: **212 876-6789**

*E-Mail: **carol.bienstock@mssm.edu**

D. ♦Approximate number of full time equivalent positions devoted to the IRB's administrative activities: **17**

E. ♦Approximate number of all active protocols (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months): **1800**

F. ♦Approximate number of active protocols conducted or supported by HHS (e.g., the National Institutes of Health, Centers for Disease Control and Prevention, etc.) (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months): **150**

G. ‡For IRBs that review, or intend to review, protocols involving products regulated by the Food and Drug Administration (FDA) (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months):

‡i) Approximate number of active protocols involving FDA-regulated products: **360**

‡ii) Types of FDA-regulated products involved in FDA protocols include (check all that apply):

<input checked="" type="checkbox"/>	human drugs	food additives
<input checked="" type="checkbox"/>	medical devices	color additives
<input checked="" type="checkbox"/>	biological products	other

Specify:

H. IRB Chairperson

*First Name: **Ilene** Middle Initial: *Last Name: **Wilets**

Earned Degree(s): **PhD** Title or Position: **IRB Chairperson**

*Mailing Address (if different from the Mailing Address in section 3):

IRB, 1 Gustave L Levy Place Box 1075

*City: **New York** *State/Province **NY** *Zip/Postal Code: **10029**

*Country (if outside the U.S.):

*Phone: **212 659-8980** *FAX: *E-Mail: **ilene.wilets@mssm.edu**

I. ♦IRB Roster Form: Completion of the IRB Roster Form is required if your IRB is designated on a Federalwide assurance submitted to OHRP. Otherwise, it is optional.

Member Name (Last, First)	Sex M/F	Earned Degree(s)	Scientist (S) or Non-scientist (N)	Primary Scientific or Non-Scientific Specialty	Affiliation with Institution(s) Y/N	Comments
Wilets, Ilene	F	PhD	Y	Emergency Medicine, GCRC Advocate	Y	Mitropoulou, scientif member of any board to maintain quorum, chair mtg
Itzkowitz, Steven	M	MD	Y	Gastroenterology	Y	alternate for Ullman, Odin
Mitropoulou, Vivian	F	MA	Y	Psychiatry	Y	alternate for Wilets
Sung, Max	M	MD	Y	Gene Therapy, Molecular Medicine, Oncolo	Y	alternate for Germain, Malone, Smith, Willner
Rojas, Mary	F	Ph.D.	Y	Adolescent Health, Psychiatry, Health Po	Y	alt Sacks, Weissman, Nasisi, Wilets, Mitropoulou, Golden, Willner
Derman, Kaye	F	N/A	N	volunteer services	Y	alternate for nonscientific members of any board
Frierson, Sarah	F	N/A	N	non-scientific	N	alternate for nonscientific members of any board
Germain, Doris	F	PhD	Y	Oncology	Y	alternate for Sung, Grunwald
Cohen, Ivy	F	BS	N	Pharmacy	Y	alternate for Meyer
Emanuel, Patrick	M	MD	Y	Dermatology/Pathology	Y	alt for Bershad
Singh, Gobind	M	B.A.	Y	Medical/Ph.D. Student	Y	
Sikora, Andrew	M	MD, PhD	Y	Otolaryngology	Y	Alt for Altman, Malkin
Smith, Cardinale	F	MD	Y	Oncology, Hematology	Y	Alt for Sung, Grunwald, Malone
Yanagisawa, Robert	M	MD	Y	Medicine, Endocrinology, Diabetes	Y	Alt for Adelson, Sachar, Schlondorff, Reich
Stulman, James	M	MD	Y	Internal Medicine	Y	Alt Reich,Schlondorff,Sachar,Klein, Kerr, Kalb, Malone,Thomas,Adelson
Cantor, Joshua	M	PhD	Y	Rehab Medicine, Psychology	Y	Alt for Thomas, Ambrose, psych: Mitropoulou
Willner, Judith	F	MD	Y	Genetics, Pediatrics	Y	Alt for Rojas, Sung, Wasserstein, Weintraub
McKay, Mary	F	PhD, MSW	Y	Psychiatry, Social Work	Y	Alt for Martin, Ernst, Mitropoulou
Factor, Stephanie	F	MD, MPH	Y	Infectious Diseases, Medicine	Y	Alt for Sacks, Klein, Tosi
Kalb, Thomas	M	MD	Y	Internal Medicine, Pulmonary, Critical C	Y	Alt Reich,Schlondorff,Sachar,Kerr, Stulman, Malone,Adelson,Thomas

Alternative Members

Banchik, Rebecca		F	BA	IRB Administration	Y	alternate for nonscientific members of any board
Bienstock, Carol		F	BA	Human Research Protection, Clinical Rese	Y	alternate for nonscientific members of any board

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Public burden for this collection of information is estimated to average two hours for a new FWA filing and less than an hour for an FWA renewal or update. 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 537H, 200 Independence Avenue, SW., Washington, DC 20201. Do not return the completed form to this address.

Do not return the completed form to this address.