

IORG #: **IORG0000124**  
Institution: **Icahn School of Medicine at Mount Sinai**  
Expires: **11/15/2025**

OMB No. 0990-0279  
Approved for use through June 30, 2025

**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 to be used for the following purposes:**

- 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/search.aspx> 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: **Icahn School of Medicine at Mount Sinai**

\*Mailing Address: **One Gustave L. Levy Place Box 1081**

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

**150 E. 42nd Street, 10th Floor, Ste. 10B**

\*City: **New York**

\*State/Province: **NEW YORK**

\*Zip/Postal Code: **10029**

\*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; President, Academic Affairs,  
MSHS**

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

**One Gustave Levy Place Box 1081**

**ATTENTION: IRB**

\*City: **New York**

\*State/Province: **NEW YORK**

\*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: **Jake**

Middle Initial:

\*Last Name: **Sutera**

Earned Degree(s): **CIP**

Title or Position: **IRB Manager**

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

**Icahn School of Medicine at Mount Sinai**

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

**One Gustave L. Levy Place Box 1081**

\*City: **New York**

\*State/Province: **NEW YORK**

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

\*Country (if outside the

\*Phone: **212 824-8200**

\*FAX: **212 876-6789**

\*E-Mail: **jake.sutera@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: **IRB00000204**

(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/search.aspx> 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

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

**One Gustave L. Levy Place Box 1081**

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

**150 E. 42nd Street, 10th Floor, Ste. 10B**

\*City: **New York**                      \*State/Province: **NEW YORK**                      \*Zip/Postal Code: **10029-6754**

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

\*Phone: **212 824-8200**                      \*FAX: **212 876-6789**                      \*E-Mail: **jake.sutera@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	<input type="checkbox"/> food additives
<input checked="" type="checkbox"/> medical devices	<input type="checkbox"/> color additives
<input checked="" type="checkbox"/> biological	<input type="checkbox"/> other
	Specify

H. IRB Chairperson

\*First Name: **Theodore** Middle Initial: \*Last Name: **Bania**

Earned Degree(s): **M.D.** Title or Position: **Chairperson, IRB/Associate Director, PPHS**

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

**One Gustave L. Levy Place  
Box 1081**

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

Country (if outside the U.S.):

\*Phone: **212 824-8200** FAX: **212 876-6789** \*E-Mail: **Theodore.Bania@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.

<b>Member Name (Last, First)</b>	<b>Sex M/F</b>	<b>Earned Degree(s)</b>	<b>Scientist (S) Non-scientist (N)</b>	<b>Primary Scientific or Non-Scientific Specialty</b>	<b>Affiliation with Institution(s) Y/N</b>	<b>Comments</b>
Bania, Theodore	M	M.D.	S	Emergency Medicine	Y	
Starr, Jay	M	JD, MBA	N	Business	N	
Mitropoulou, Vivian	F	MA	S	Psychiatry, research design	Y	
Weintraub, Andrea	F	MD	S	Pediatrics, Neonatology	Y	representative: children, pregnant women
Delman, Bradley	M	MD	S	Radiology	Y	
Tosi, Michael	M	MD	S	Pediatrics, Infectious Diseases	Y	representative: children
McBride, Russell	M	Ph.D, MPH	S	Epidemiology	Y	experience with economically disadvantaged persons
Cohen, Ivy	F	BS	S	Pharmacy	Y	
Rothschild, Barbara	F	BA	N	Administration	N	
Sachmechi, Issac	M	MD	S	Endocrinology	Y	
Ungaro, Ryan	M	MD	S	Gastroenterology	Y	
Krone, Beth	F	PhD	S	Psychiatry	Y	
Khalil, Susan	F	MD	S	Obstetrics	Y	Representative: Pregnant women; Experience with economically disadvantaged
Lema, Gareth	M	MD	S	Ophthalmology	Y	
Shah, Lasha	F	MD	S	Psychiatry	Y	Representative: children, cognitively impaired
Cohen, Bevin	F	PhD, MS, MPH	S	Nursing	Y	epidemiologist
Richard, Shambavi	F	MD	S	Oncology	Y	
Pintova, Sofya	F	MD	S	Oncology	Y	
Naib, Tara	F	MD, MPH	S	Cardiology	Y	

**Alternative Members**

Shemesh, Eyal	M	M.D.	S	Pediatrics, child and adult Psychiatry	Y	representative: children, cognitively impaired, mentally disabled
Friedlander, Philip	M	MD	S	Oncology	Y	Alternate for Scientific member 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 comparable 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: **IRB00004094**

(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/search.aspx> 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**

C. Location of the IRB

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

**One Gustave L. Levy Place Box 1081**

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

**150 E. 42nd Street, 10th Floor, Ste. 10B**

\*City: **New York**

\*State/Province: **NEW YORK**

\*Zip/Postal Code: **10029**

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

\*Phone: **212 824-8200**

\*FAX: **212 876-6789**

\*E-Mail: **jake.sutera@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	other
	Specify

H. IRB Chairperson

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

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 1081**

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

Country (if outside the U.S.):

\*Phone: **212 824-8200** FAX: **212 876-6789** \*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.

<b>Member Name (Last, First)</b>	<b>Sex M/F</b>	<b>Earned Degree(s)</b>	<b>Scientist (S) Non-scientist (N)</b>	<b>Primary Scientific or Non-Scientific Specialty</b>	<b>Affiliation with Institution(s) Y/N</b>	<b>Comments</b>
Martin, Glenn	M	MD	S	Psychiatry, HIPAA, Medical Informatics	Y	expertise in cognitive impairment
Jennex, Lori	F	MA	S	Anthropology	Y	
Guidry, John	M	Ph.D.	S	Political science, CBPR, HIV	N	experience with children; disadvantaged populations; disaster preparedness; alt
Sutera, Jake	M	BA, CIP	N	Human Subjects Protections	Y	
Bressler, Toby	F	PhD, RN, OCN	S	Oncology Nursing	Y	nursing

**Alternative Members**

Kucera, Jennifer	F	MS, CIP	S	Human Subjects Protections	Y	
Richmond, Megan	F	BS, CIP	N	Human Subjects Protections	Y	Alternate for any non-scientific member of any board
Roman, Cyndi	F	BA, CIP	N	Human Subjects Protection	Y	Alternate for any non-scientific member of any board
Datko, Joseph	M	MS, CIP	S	Human Subjects Protection	Y	

**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 comparable 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: **IRB00005471**

(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/search.aspx> 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 #3 - Board A**

C. Location of the IRB

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

**One Gustave L. Levy Place Box 1081**

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

**150 E. 42nd Street, 10th Floor, Ste. 10B**

\*City: **New York**                      \*State/Province: **NEW YORK**                      \*Zip/Postal Code: **10029**

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

\*Phone: **212 824-8200**                      \*FAX: **212 867-6789**                      \*E-Mail: **jake.sutera@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	other
	Specify

H. IRB Chairperson

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

Earned Degree(s): **MD** Title or Position: **IRB Chairperson; Associate Dean Research**

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

**Institutional Review Board 1 Gustave L Levy Box 1081**

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

Country (if outside the U.S.):

\*Phone: **212 824-8200** FAX: **212 876-6789** \*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.

<b>Member Name (Last, First)</b>	<b>Sex M/F</b>	<b>Earned Degree(s)</b>	<b>Scientist (S) Non-scientist (N)</b>	<b>Primary Scientific or Non-Scientific Specialty</b>	<b>Affiliation with Institution(s) Y/N</b>	<b>Comments</b>
Martin, Glenn	M	MD	S	Psychiatry, Medical Informatics, HIPAA	Y	expertise in cognitive impairment
Reich, Lawrence	M	MD, Ph.D	S	Internal Medicine, Primary Care	Y	
Sacks, Henry	M	MD, PhD	S	Community Medicine	Y	
Jandorf, Lina	F	MA	S	Sociology	Y	experience with economically disadvantaged persons, community outreach
Manasia, Anthony	M	MD	S	Critical Care	Y	pregnant women, cognitively impaired, disabled individuals, critically ill
Sicherer, Scott	M	MD	S	Pediatrics	Y	representative: Children
Kremyanskaya, Marina	F	MD	S	oncology	Y	
Jean, Raymonde	F	MD	S	Medicine - Pulmonary	Y	
Royal, Dorian	F	DNP, ACNP-BC	S	Nursing	Y	children rep
Cravedi, Paolo	M	MD, PhD	S	Nephrology, Transplant	Y	
Shariat, Ali	M	MD, MS	S	Anesthesiology	Y	
Bressler, Toby	F	PhD, RN, OCN	S	Oncology, Nursing	Y	
Zimmerman, Richard	M	JD	N	Legal	N	
Marron, Thomas	M	MD, PhD	S	Oncology	Y	
Hirten, Robert	M	MD	S	Gastroenterology	Y	
Hirsch, Fred	M	MD, PhD	S	Oncology	Y	
Craven, Mary-Abigail	F	MD	S	Ophthalmology	Y	
Mashni, Susan	F	BS, PharmD	S	Pharmacy	Y	
Ambrosia, Todd	M	DNP, MSN	S	Nursing	Y	

**Alternative Members**

Eshikena, Marilyn	F	MS, CIP	S	Human Subjects Protections	Y	alt for any scientific member on any board
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**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?

Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: **IRB00005472**

(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/search.aspx> 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

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

**One Gustave L. Levy Place Box 1081**

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

**150 E. 42nd Street, 10th Floor, Ste. 10B**

\*City: **New York**                      \*State/Province: **NEW YORK**                      \*Zip/Postal Code: **10029-6754**

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

\*Phone: **212 824-8200**                      \*FAX: **212 876-6789**                      \*E-Mail: **jake.sutera@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	other
	Specify

H. IRB Chairperson

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

Earned Degree(s): **MD** Title or Position: **Chair, IRB; Associate Dean for Research**

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

**IRB, 1 Gustave L Levy Place Box 1081**

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

Country (if outside the U.S.):

\*Phone: **212 824-8200** FAX: **212 876-6789** \*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.

<b>Member Name (Last, First)</b>	<b>Sex M/F</b>	<b>Earned Degree(s)</b>	<b>Scientist (S) Non-scientist (N)</b>	<b>Primary Scientific or Non-Scientific Specialty</b>	<b>Affiliation with Institution(s) Y/N</b>	<b>Comments</b>
Martin, Glenn	M	MD	S	Psychiatry, HIPAA, Medical Informatics	Y	expertise in cognitive impairment
Vezina, Maria	F	EdD,RN	S	Nursing Education	Y	
Ernst, Carrie	F	MD	S	Psychiatry	Y	pregnant women, diminished capacity
Factor, Stephanie	F	MD, MPH	S	Epi Research with children, infectious d	Y	rep: children
Shao, Theresa	F	MD	S	Oncology	Y	
Mack, Theresa	F	MD	S	Medicine - Infectious Diseases	Y	alt any scientific member any board
Kornberg, Robert	M	MD	S	Medicine - Cardiology	Y	alt any scientific member any board
Strauss, Neil	M	none	N	computing systems, engineering	N	
Dunn, Dallas	M	MD	S	Infectious Diseases	Y	
Blum, Ronald	M	MD	S	Oncology	Y	
Lin, Jun	M	MD, PhD	S	Ophthalmology	Y	
Argiriadi, Pamela	F	MD	S	Radiology	Y	
Sin, Billy	M	PharmD, MBA	S	Pharmacy	Y	
Mahoney, Christine	F	DNP, RN	S	Nursing	Y	

#### **Alternative Members**

Lindeman, Max	M	MSW, PhD	S	Social Work	N	prisoner rep
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#### **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 comparable 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: **IRB00005473**

(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/search.aspx> 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

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

**One Gustave L. Levy Place Box 1081**

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

**150 E. 42nd Street, 10th Floor, Ste. 10B**

\*City: **New York**

\*State/Province: **NEW YORK**

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

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

\*Phone: **212 824-8200**

\*FAX: **212 876-6789**

\*E-Mail: **jake.sutera@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	<input type="checkbox"/> food additives
<input checked="" type="checkbox"/> medical devices	<input type="checkbox"/> color additives
<input checked="" type="checkbox"/> biological	<input type="checkbox"/> other
	Specify

#### H. IRB Chairperson

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

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

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

**1 Gustave L. Levy Place Box 1081**

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

Country (if outside the U.S.):

\*Phone: **212 824-8200** FAX: **212 876-6789** \*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.

<b>Member Name (Last, First)</b>	<b>Sex M/F</b>	<b>Earned Degree(s)</b>	<b>Scientist (S) Non-scientist (N)</b>	<b>Primary Scientific or Non-Scientific Specialty</b>	<b>Affiliation with Institution(s) Y/N</b>	<b>Comments</b>
Wilets, Ilene	F	PhD	S	Research Ethics	Y	
Mitropoulou, Vivian	F	MA	S	Psychiatry	Y	
Sung, Max	M	MD	S	Gene Therapy, Molecular Medicine, Oncolo	Y	
Yanagisawa, Robert	M	MD	S	Medicine, Endocrinology, Diabetes	Y	
Beckman, Fern	F	MBE	S	Monitoring clinical trials, ethics	N	
DeLaet, David	M	MD,MPH	S	Pediatrics, Internal Medicine	Y	experience with children, pregnant women,cognitively impaired, economically disa
Gomez, Jorge	M	MD	S	Oncology	Y	
Bania, Theodore	M	MD	S	Emergency Medicine	Y	
Katz, Daniel	M	MD	S	Anesthesiology	Y	
Altman, Deena	F	MD	S	Infectious Diseases, Genetics	Y	
Cowan, Ethan	M	MD, MS	S	Emergency Medicine	Y	
Smith, Roland Theodore	M	MD	S	Ophthalmology	Y	
Ben-Zacharia, Aliza	F	PhD	S	Nursing	Y	
Little, Lynn	F	BA	N	Community	N	
Nowlin, Sarah	F	PhD, MSN, BSN	S	Nursing	Y	
Appel, Jacob	M	MD, MPH, JD	S	Psychiatry	Y	experience with cognitively impaired
Samarbakhsh, Samira	F	PharmD, MHS	S	Pharmacy	Y	
Porras, Christian	M	BS	S	Student	Y	

#### **Alternative Members**

#### **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.

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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: **IRB00008887**

(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/search.aspx> 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 #6**

C. Location of the IRB

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

**One Gustave L. Levy Place Box 1081**

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

**150 E. 42nd Street, 10th Floor, Ste. 10B**

\*City: **New York**

\*State/Province: **NEW YORK**

\*Zip/Postal Code: **10029**

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

\*Phone: **212 824-8200**

\*FAX: **212 876-6789**

\*E-Mail: **jake.sutera@mssm.edu**

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

**1**

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):

**5**

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

**0**



under an expedited review procedure during the preceding 12 months):

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

**0**

‡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      | other           |
|   | Specify         |

H. IRB Chairperson

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

Earned Degree(s): **MD** Title or Position: **Chair, IRB; Assoc. Dean for Research**

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

**1 Gustave L. Levy Place Box 1081**

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

Country (if outside the U.S.):

\*Phone: **212 824-8200** FAX: **212 876-6789** \*E-Mail: **glenn.martin@mssm.edu**

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<b>Member Name (Last, First)</b>	<b>Sex M/F</b>	<b>Earned Degree(s)</b>	<b>Scientist (S) Non-scientist (N)</b>	<b>Primary Scientific or Non-Scientific Specialty</b>	<b>Affiliation with Institution(s) Y/N</b>	<b>Comments</b>
Martin, Glenn	M	MD	S	Psychiatry, HIPAA, Medical Informatics	Y	cognitively impaired
Hall, Courtney	M	MBA,JD	N	Business	N	former player in NFL
Mayer, Thom	M	MD, FACEP, FAAP	S	Sports Medicine	N	NFL Players Association representative
Jennex, Lori	F	MA	S	Human Subject protections	Y	
Kucera, Jennifer	F	MS, CIP	S	Human Subjects Protection	Y	

#### **Alternative Members**

#### **NOTES:**

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Public burden for this collection of information is estimated to average one hour for an initial IRB registration, and thirty minutes for updating or renewing the registration of a previously registered IRB. 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.*