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)?
   [X] 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/daq-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):
     345 E 102nd St, Suite 200
   *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:  Rachel  Middle Initial:  C  *Last Name:  Lally
   Earned Degree(s):  MPH, CIP  Title or Position:  Assistant Director, Regulatory &
   Administrative Affairs, PPHS
   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 U.S.):
     *Phone:  212 824-8200  *FAX:  212 876-6789  *E-Mail:  rachel.lally@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? [ X ] 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/daq-2.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):

345 E 102nd St, Suite 200

*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: **rachel.lally@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):

- [X] human drugs
- [X] medical devices
- [X] biological
- food additives
- color additives
- 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: Tbania@chpnet.org
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.

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<thead>
<tr>
<th>Member Name</th>
<th>Sex</th>
<th>Earned Degree(s)</th>
<th>Scientist (S)</th>
<th>Primary Scientific or Non-Scientific Specialty</th>
<th>Affiliation with Institution(s)</th>
<th>Comments</th>
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<td>Cummins, Paul</td>
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<td>S</td>
<td>Philosophy, biomedical ethics</td>
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<td>N</td>
<td>Journalist, patient, research subject</td>
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<td>Shemesh, Eyal</td>
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<td>M.D.</td>
<td>S</td>
<td>Pediatrics, child and adult Psychiatry</td>
<td>Y</td>
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</table>

Alternative Members

- Friedlander, Philip: Alternate for Scientific member of any board
- Shemesh, Eyal: Representative: children, cognitively impaired, mentally disabled

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?  
   [ X ] 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/daqistaff.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):  
   **345 E 102nd St, Suite 200**

   *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: rachel.lally@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):

- X human drugs
- X medical devices
- X biological

Specify: food additives, color additives, other

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.

<table>
<thead>
<tr>
<th>Member Name (Last, First)</th>
<th>Sex</th>
<th>Earned Degree(s)</th>
<th>Scientist (S)</th>
<th>Non-scientist (N)</th>
<th>Primary Scientific or Non-Scientific Specialty</th>
<th>Affiliation with Institution(s) Y/N</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Martin, Glenn</td>
<td>M</td>
<td>MD</td>
<td>S</td>
<td></td>
<td>Psychiatry, HIPAA, Medical Informatics</td>
<td>Y</td>
<td>expertise in cognitive impairment</td>
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<td>Jennex, Lori</td>
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<td>MA</td>
<td>S</td>
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<td>Anthropology</td>
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<tr>
<td>Hammer, Marilyn</td>
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<td>S</td>
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<td>Banchik, Rebecca</td>
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<td>BA, CIP</td>
<td>N</td>
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<td>human subject protections</td>
<td>Y</td>
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<td>Guidry, John</td>
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<td>Ph.D.</td>
<td>S</td>
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<td>Political science, CBPR, HIV</td>
<td>N</td>
<td>experience with children; disadvantaged populations; disaster preparedness; alt</td>
</tr>
</tbody>
</table>

Alternate Members

| Lally, Rachel             | F   | MPH, CIP        | S             | human subjects protections | N                                 | alternate for any 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.
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A. *Is this a renewal or update of a registration for an IRB already registered with HHS?*

[ X ] 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/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

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

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

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

**345 E 102nd St, Suite 200**

*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: rachel.lally@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
procedure during the preceding 12 months):

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):

- [X] human drugs
- [X] medical devices
- [X] biological
- food additives
- color additives
- 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
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<tr>
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<th>Sex</th>
<th>Earned Degree(s)</th>
<th>Scientist (S) or Non-Scientist (N)</th>
<th>Primary Scientific Affiliation with Institution(s)</th>
<th>Comments</th>
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<td>expertise in cognitive impairment</td>
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**Alternative Members**

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**NOTES:**

pregnant women, cognitively impaired, disabled individuals, critically ill experience with economically disadvantaged persons, community outreach

children rep representative: Children

alt for any nonscientific member on any board

alt for any scientific member on any board

Alternate for Scientific member of any board
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?*

[ X ] 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.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):*

**345 E 102nd St, Suite 200**

*Cities: 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: rachel.lally@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:

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

- human drugs
- medical devices
- biological
- food additives
- color additives
- other

Specify:

H. IRB Chairperson

*First Name: Glenn
*Middle Initial: M
*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.

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<th>Member Name (Last, First)</th>
<th>Sex</th>
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<th>Primary Scientific or Non-Scientific Specialty</th>
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<th>Comments</th>
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<td>Vezina, Maria</td>
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<td>RN, MS</td>
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<td>S</td>
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<td>rep: children</td>
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<td>S</td>
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<td>MD</td>
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**Alternative Members**

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<th>Member Name (Last, First)</th>
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A. *Is this a renewal or update of a registration for an IRB already registered with HHS?
   [ X ] 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/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 #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):
   345 E 102nd St, Suite 200
   *City: New York *State/Province: NEW YORK *Zip/Postal Code: 10029-6754
   *Phone: 212 824-8200 *FAX: 212 876-6789 *E-Mail: rachel.lally@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

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   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:

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

- human drugs
- medical devices
- biological
- food additives
- color additives
- other

Specify:

360

H. IRB Chairperson

*First Name: Ilene  Middle Initial: M  *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
New York  NEW YORK  10029

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
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<th>Primary Scientific or Non-Scientific Specialty</th>
<th>Affiliation with Institution(s) Y/N</th>
<th>Comments</th>
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Alternative Members

| Prasad Hayes, Monica      | F   | MD               | S                          | Gynecologic Oncology                        | Y                                 | Alternate for Scientific member of any board |

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

[ X ] 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/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 #6**

C. Location of the IRB

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

**345 E 102nd St, Suite 200**

*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**

*Phone: **212 824-8200**  
*FAX: **212 876-6789**  
*E-Mail: **rachel.lally@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 under an expedited review procedure during the preceding 12 months): **0**
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: 0

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

- [x] human drugs
- [x] medical devices
- [x] biological
- [ ] food additives
- [ ] color additives
- [ ] 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
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.

<table>
<thead>
<tr>
<th>Member Name (Last, First)</th>
<th>Sex</th>
<th>Earned Degree(s)</th>
<th>Scientist (S) Non-scientist (N)</th>
<th>Primary Scientific or Non-Scientific Specialty</th>
<th>Affiliation with Institution(s) Y/N</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Martin, Glenn</td>
<td>M</td>
<td>MD</td>
<td>S</td>
<td>Psychiatry, HIPAA, Medical Informatics Business</td>
<td>N</td>
<td>cognitively impaired</td>
</tr>
<tr>
<td>Hall, Courtney</td>
<td>M</td>
<td>MBA, JD</td>
<td>N</td>
<td>Sports Medicine</td>
<td>N</td>
<td>former player in NFL</td>
</tr>
<tr>
<td>Mayer, Thom</td>
<td>M</td>
<td>MD, FACEP, FAAP</td>
<td>S</td>
<td>Human Subject protections human subjects protections</td>
<td>N</td>
<td>NFL Players Association representative</td>
</tr>
<tr>
<td>Jennex, Lori</td>
<td>F</td>
<td>MA</td>
<td>S</td>
<td></td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Lally, Rachel</td>
<td>F</td>
<td>MPH, CIP</td>
<td>S</td>
<td></td>
<td>Y</td>
<td></td>
</tr>
</tbody>
</table>

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.

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?  
[ X ] Yes.  Provide the IRB registration number previously assigned to this IRB by OHRP: **IRB00009764**  
(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.nih.gov/search/search.aspx](http://ohrp.nih.gov/search/search.aspx) or contact OHRP using the contact information at [http://www.hhs.gov/ohrp/dqi-staff.html](http://www.hhs.gov/ohrp/dqi-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):  
**Icahn School of Medicine at Mount Sinai IRB #7**

C. Location of the IRB  
*Mailing Address (if different from the Mailing Address in section 3):*  
**One Gustave L. Levy Place Box 1081**

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*Zip/Postal Code: 10029  
*Country (if outside the U.S.):*  
*Phone: 212 824-8200  
*FAX: 212 876-6789  
*E-Mail: rachel.lally@mssm.edu*

D. Approximate number of full time equivalent positions devoted to the IRB’s administrative activities:  
2

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):  
10

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  
5
continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months):

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:

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

- human drugs
- medical devices
- biological
- food additives
- color additives
- 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):

**One Gustave L. Levy Place**

**Box 1081**

**New York, NY 10029**

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

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*Phone: **212 824-8200**  FAX: **212 876-6789**  *E-Mail: **glenn.martin@mssm.edu**
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<th>Earned Degree(s)</th>
<th>Scientist (S) or Non-scientist (N)</th>
<th>Primary Scientific or Non-Scientific Specialty</th>
<th>Affiliation with Institution(s) Y/N</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Martin, Glenn</td>
<td>M</td>
<td>MD</td>
<td>S</td>
<td>Psychiatry, HIPAA, Medical Informatics</td>
<td>Y</td>
<td>expertise in cognitive impairment</td>
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<tr>
<td>Guidry, John</td>
<td>M</td>
<td>PhD</td>
<td>S</td>
<td>CBPR, HIV, political science</td>
<td>N</td>
<td>Representative: disadvantaged populations, children</td>
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<td>Schneipf, Phyllis</td>
<td>F</td>
<td>MS</td>
<td>N</td>
<td>Healthcare administration</td>
<td>Y</td>
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<td>Cohen, Roger</td>
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<td>MD</td>
<td>S</td>
<td>Oncology</td>
<td>N</td>
<td>representative: economically disadvantaged, pts. with advanced cancer, exp with</td>
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<td>M</td>
<td>MD, PhD</td>
<td>S</td>
<td>Pathology</td>
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<td>Bania, Theodore</td>
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<td>MD</td>
<td>S</td>
<td>Emergency Medical</td>
<td>Y</td>
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<td>Gomez, Jorge</td>
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<td>S</td>
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<td>Y</td>
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<td>F</td>
<td>MD</td>
<td>S</td>
<td>Pediatrics</td>
<td>Y</td>
<td>children</td>
</tr>
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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.