

Submission#: **32749**  
IORG#: **IORG0000196**  
Institution: **U of Pittsburgh**

OMB No. 0990-0279  
Approved for use through August 31, 2015

## **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? IORG0000196**

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: **U of Pittsburgh**

\*Mailing Address: **3500 Fifth Avenue  
Hieber Building**

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

\*City: **Pittsburgh** \*State/Province: **PENNSYLVANIA** \*Zip/Postal Code: **15213**

\*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: **Randy** Middle Initial: **P** \*Last Name: **Juhl**

Earned Degree(s): **PhD** Title or Position: **Vice Chancellor for Research  
Conduct & Compliance**

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

**132 Cathedral of Learning**

\*City: **Pittsburgh** \*State/Province: **PENNSYLVANIA** \*Zip/Postal Code: **15261  
A**

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

\*Phone: **412 624-9111** \*FAX: **412 624-6903** \*E-Mail: **rjuhl@pitt.edu**

**5. Contact Person Providing this Registration Information**

\*First Name: **Melissa** Middle Initial: \*Last Name: **Miklos**

Earned Degree(s): **BS, CIP** Title or Position: **Program Manager**

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

**University of Pittsburgh IRB**

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

**3500 Fifth Avenue  
105 Hieber Building**

\*City: **Pittsburgh** \*State/Province: **PENNSYLVANIA** \*Zip/Postal Code: **15213**

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

\*Phone: **412 383-1480** \*FAX: **412 383-1508** \*E-Mail: **miklosm@upmc.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: **IRB00000319**

(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):

**U of Pittsburgh IRB #1 - A**

C. Location of the IRB

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

**3500 Fifth Avenue  
Hieber Building**

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

\*City: **Pittsburgh**                      \*State/Province: **PENNSYLVANIA**      \*Zip/Postal Code: **15213**

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

\*Phone: **412 383-1480**      \*FAX: **412 383-1508**                      \*E-Mail: **miklosm@upmc.edu**

D. ♦Approximate number of full time equivalent positions devoted to the IRB's administrative activities: **20**

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): **7580**

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): **694**

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:

**283**

‡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: **Ronald** Middle Initial: \*Last Name: **Shapiro**

Earned Degree(s): **M.D.** Title or Position: **IRB Chairperson**

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

**3500 Fifth Avenue, Ground Level**

City: **Pittsburgh** State/Province: **PENNSYLVANIA** Zip/Postal Code: **15213**

Country (if outside the U.S.):

\*Phone: **412 383-1480** FAX: **412 383-1508** \*E-Mail: **shapiror@upmc.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>
Shapiro, Ronald	M	MD	S	Transplant Surgery	Y	
Soran, Ozlem	F	MD	S	Cardiology	Y	
Appleman, Leonard	M	MD, PhD	S	hem/onc	Y	
Irrgang, James	M	PhD, PT, ATC	S	Orthopedics, PT, Rehabilitation	Y	
Gibson, Michael	M	MD	S	Hematology/Oncology	Y	
Fink, Barbara	F	BS, MS	S	Ophthalmology Research	Y	
Schwartz, Miriam	F	none	N	support groups	N	
Curry, Scott	M	MD	S	infectious disease	Y	
Klatt, Brian	M	MD	S	orthopedic surgery	Y	
Shapiro, Ronald	M	MD	S	transplant surgery	Y	
Dudjak, Linda	F	RN, PhD	S	nursing, oncology	Y	
Veraldi, Kristen	F	MD, PhD, FCCP	S	Pulmonary, Allergy, & CCM	Y	
DeSantes, Lisa	F	BS, CIP	N	IRB regulations, study coordination	Y	
Summersgill, Kurt	M	DDS, PhD	S	dental medicine, pathology	Y	
Raman, Venkataramanan	M	PhD	S	pharmacy	Y	
Schuchert, Matt	M	MD	S	thoracic surgery	Y	
Gildengers, Ariel	M	MD	S	psychiatry	Y	
Yip, Lin	F	MD	S	surgical oncology, endocrine surgery	Y	
Dilts, Robert	M	PhD	N	Mathematics	Y	
Howland, Robert	M	MD	S	Psychiatry	Y	
Klain, Miroslav	M	MD, PhD	S	Anesthesia	Y	
Mitchell-O'Brien, Leeann	F	JD	N	Health and Hospital Law	N	
<b>Alternative Members</b>						
LeMenager, Michelle	F	BS	N	IRB regulations	Y	any non-scientific member
Tan, Henkie	M	MD, PhD	S	Transplant Surgery	Y	any physician member
Wenzel, Sally	F	MD	S	Pulmonary, Allergy & Critical Care Medicine	Y	any physician member
Grabowski, Erin	F	BS, CIP	N	IRB regulations, psychology	Y	any non-scientific member
Orndoff, Patricia	F	RN, MEd	S	Nursing	Y	any other scientific member
Landolina, Nicholas	M	MPM, M.Ed.	N	management,	Y	any non-scientific member

Hurst, Kathleen	F	N/A	N	non-scientific administrative	Y	any non-scientific membe
Miklos, Melissa	F	BS, CIP	N	IRB regulations	Y	any non-scientific membe
Carey, Thomas	M	MSW, CIP	S	Social Work, IRB regulations	Y	any other scientific memt
Navratil, Judith	F	BA	N	IRB regulations	Y	any non-scientific membe
Moss, Deborah	F	MD	S	pediatrics	Y	any physician member
McKaveney, Theresa	F	BS	N	IRB regulations	Y	any non-scientific membe
Okonkwo, David	M	MD, PhD	S	neurosurgery	Y	any physician member
Pinsky, Michael	M	MD	S	pulmonary & critical care medicine	Y	any physician member
Nebes, Robert	M	PhD	S	geriatric psychiatry	Y	any other scientific memt
Ivanusic, Carolyn	F	BS, MSW	N	IRB regulations	Y	any non-scientific membe
Brufsky, Adam	M	MD, PhD	S	Hematology/Oncology	Y	any physician member
Hollabaugh, Kim	F	MSN, RN	S	nursing	Y	any other scientific memt
Greenaway, Patty	F	RN, BSN	S	oncology nursing	Y	any other scientific memt
Lee, Ann	F	MSN, CRNP, CIP	S	cardiology, heart/lung transplant	Y	any other physician meml
Holloway, Melanie	F	RN, BSN	S	pediatric nursing	Y	anoy other scientific mem
Manders, Ernest	M	MD	S	plastic & reconstructive surgery	Y	any physician member
Valenti, Shannon	F	BS, MBA	N	Research regulations	Y	any non-scientific membe
Patsy, Simon	F	RN, BS	S	pulmonary transplant, oncology	Y	any other scientific memt
Wei, Lawrence	M	MD	S	cardiothoracic surgery	Y	any physician member
Tarhini, Ahmad	M	MD, MS	S	Hematology/Oncology	Y	any physician member
Guido, Richard	M	MD	S	OB/GYN	Y	University of Pittsburgh I Executive Chairman
Pischke, Jack	M	MSW	N	incarceration	Y	prisoner representative

## 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?

[ X ] Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: **IRB00000320**

(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):

**U of Pittsburgh IRB #2 - B**

C. Location of the IRB

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

**3500 Fifth Avenue  
Hieber Building**

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

\*City: **Pittsburgh**                      \*State/Province: **PENNSYLVANIA**      \*Zip/Postal Code: **15213**

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

\*Phone: **412 383-1480**      \*FAX: **412 383-1508**                      \*E-Mail: **miklosm@upmc.edu**

D. ♦Approximate number of full time equivalent positions devoted to the IRB's administrative activities: **20**

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): **7580**

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): **694**

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

**283**

‡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: **Margaret** Middle Initial: \*Last Name: **Hsieh**

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

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

**3500 Fifth Avenue, Ground Level**

City: **Pittsburgh** State/Province: **PENNSYLVANIA** Zip/Postal Code: **15213**

Country (if outside the U.S.):

\*Phone: **412 383-1480** FAX: **412 383-1508** \*E-Mail: **hsiehm@upmc.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>
Hsieh, Margaret	F	MD	S	Emergency Medicine	Y	
Mathias, Ann	F	JD, MHSA	N	Corporate Compliance	Y	
Gallagher, Denise	F	MD	S	ophthalmology	Y	
Yanowitz, Toby	F	MD	S	neonatology, pediatrics	Y	
Hsieh, Margaret	F	MD	S	emergency medicine	Y	
Straka, Kristin	F	MSN, RN, CPN	S	Nursing Research and Evidence Based Prac	Y	
Engh, Johnathan	M	MD	S	Neurological surgery	Y	
Olawaiye, Alexander	M	MD	S	OB/GYN, oncology	Y	
Chang, Judy	F	MD, MPH	S	OB/Gyn	Y	
Becker, Stacey	F	BS	S	cognitive psychology; Autism-Neurobiolog	Y	
Lee, Ann	F	MSN, RN, CRNP, CIP	S	cardiology, heart/lung tx	Y	
Rotondi, Armando	M	PhD	S	psychology, heath services systems	Y	
Hathaway, Bridget	F	MD	S	otolaryngology	Y	
Jessie, VanSwearingen	F	PhD	S	physical therapy	Y	
Brown, Spencer	M	PhD	S	wound healing	Y	
Chamberlin, Jennifer	F	BS	N	research coordination	Y	
Prasad, Konasale	M	MD	S	psychiatry, genetics	Y	
Hrynkiw, Nancy	F	BS	N	non-scientific community member	N	
McCormick, Nancy	F	BS, MS	N	research coordination, FDA regulations	Y	
Palmer, Catherine	F	PhD	S	Audiology	Y	
Schraut, Wolfgang	M	MD	S	Surgery	Y	
<b>Alternative Members</b>						
Davis, Jan	F	RN, PhD, CRNP	S	cardiopulmonary nursing	Y	
DeSantes, Lisa	F	BS, CIP	N	IRB regulations, study coordination	Y	any non-scientific membe
Hilmi, Ibtesam	F	MB, CHB, FRCA	S	anesthesia	Y	any physician member

Hollabaugh, Kim	F	MSN, RN	S	nursing	Y	any other scientific memb
Greenaway, Patty	F	RN, BSN	S	oncology nursing	Y	any other scientific memb
Pasculle, Anthony	M	ScD	S	Clinical Microbiology	Y	any other scientific memb
Flook, Donna	F	MSN, RN, CPN	S	pediatric nursing	Y	any other scientific memb
Libman, Ingrid	F	MD, PhD	S	pediatric endocrinology	Y	any physician member
Gingrich, Jeffrey	M	MD	S	Urology	Y	any physician member

## 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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[ ] 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):

**U of Pittsburgh IRB #3 - C**

C. Location of the IRB

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

**3500 Fifth Avenue  
Hieber Building**

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

\*City: **Pittsburgh**                      \*State/Province: **PENNSYLVANIA**      \*Zip/Postal Code: **15213**

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

\*Phone: **412 383-1480**      \*FAX: **412 383-1508**                      \*E-Mail: **miklosm@upmc.edu**

D. ♦Approximate number of full time equivalent positions devoted to the IRB's administrative activities: **20**

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): **7580**

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**283**

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- |   |                 |
|---|-----------------|
| <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: **Richard** Middle Initial: \*Last Name: **Guido**

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

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

**3500 Fifth Avenue**

City: **Pittsburgh** State/Province: **PENNSYLVANIA** Zip/Postal Code: **15213**

Country (if outside the U.S.):

\*Phone: **412 383-1480** FAX: **412 383-1508** \*E-Mail: **rguido@mail.magee.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>
Guido, Richard	M	PhD	S	neuropsychology	Y	
George, Betsy	F	RN, PhD	S	Tertiary, Critical Care	Y	
Venkataramanan, Raman	M	PhD	S	Pharmacy	Y	
Zeh, Herbert	M	MD	S	surgical oncology	Y	
Schuchert, Matt	M	MD	S	thoracic surgery	Y	
Prasad, Konasale	M	MD	S	psychiatry, genetics	Y	
Holloway, Melanie	F	RN, BSN, CIP	S	pediatric nursing	Y	
Greenaway, Patty	F	RN, BSN	S	oncology nursing	Y	
Guido, Richard	M	MD	S	OB/GYN	Y	
Miklos, Melissa	F	BS, CIP	N	IRB regulations	Y	
Ryan, Christopher	M	PhD	S	psychology, IRB regulations	Y	
Barone, Jean	F	CIP	N	IRB regulations	Y	
Appleman, Leonard	M	MD, PhD	S	Hematology/Oncolo gy	Y	
Yanowitz, Toby	F	MD	S	Pediatrics, Neonatology	Y	
Brandom, Barbara	F	MD	S	Anesthesia, Pediatrics	Y	
Hrynkiw, Nancy	F	BS	N	Non-scientific	N	
<b>Alternative Members</b>						
Hollabaugh, Kim	F	MSN, RN, CIP	S	nursing	Y	
DeSantes, Lisa	F	BS, CIP	N	IRB regulations	Y	
Lee, Ann	F	MSN, CRNP, CIP	S	cardiology, heart/lung transplant	Y	any other scientific memt

**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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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: **IRB00003491**

(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):

**U of Pittsburgh IRB #6 - F**

C. Location of the IRB

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

**3500 Fifth Avenue  
Hieber Building**

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

\*City: **Pittsburgh**                      \*State/Province: **PENNSYLVANIA**      \*Zip/Postal Code: **15213**

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

\*Phone: **412 383-1480**              \*FAX: **412 383-1508**                      \*E-Mail: **miklosm@upmc.edu**

D. ♦Approximate number of full time equivalent positions devoted to the IRB's administrative activities: **20**

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): **7580**

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): **694**

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:

**283**

‡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: **Richard** Middle Initial: \*Last Name: **Guido**

Earned Degree(s): **M.D.** Title or Position: **Chairman, IRB**

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

**3500 Fifth Avenue, Ground Level**

City: **Pittsburgh** State/Province: **PENNSYLVANIA** Zip/Postal Code: **15213**

Country (if outside the U.S.):

\*Phone: **412 383-1480** FAX: **412 383-1508** \*E-Mail: **Guido@mail.magee.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>
Guido, Richard	M	M.D.	S	OB/GYN	Y	
Barone, Jean	F	CIP	N	IRB regulations	Y	
Beers, Susan	F	PhD	S	Pediatric neuropsychology	Y	
Ryan, Christopher	M	PhD	S	psychology	Y	
Slagle, Nellie Lou	F	BA	N	non-scientist	Y	
Sweet, Robert	M	MD	S	psychiatry	Y	
Hsieh, Margaret	F	MD	S	Emergency Medicine	Y	
Zelazny, Jamie	F	MPH, RN	S	psychiatric nursing	Y	
Shapiro, Ronald	M	MD	S	Transplant Surgery	Y	
Guido, Richard	M	MD	S	OB/GYN	Y	
Oliver, D. Lamar	M	BS	N	electrical engineering, non-scientist	N	
Katz, Aviva	F	MD	S	pediatric surgery	Y	
Zeh, Herbert	M	MD	S	surgical oncology	Y	
<b>Alternative Members</b>						
Lieberman, Frank	M	MD	S	Neuro-oncology	Y	any physician member

**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: **IRB00004005**

(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):

**U of Pittsburgh IRB #7 - G**

C. Location of the IRB

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

**3500 Fifth Avenue  
Hieber Building**

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

\*City: **Pittsburgh**                      \*State/Province: **PENNSYLVANIA**                      \*Zip/Postal Code: **15213**

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

\*Phone: **412 383-1480**                      \*FAX: **412 383-1508**                      \*E-Mail: **miklosm@upmc.edu**

D. ♦Approximate number of full time equivalent positions devoted to the IRB's administrative activities: **20**

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): **7580**

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

**694**

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:

**283**

‡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: **Aviva** Middle Initial: \*Last Name: **Katz**

Earned Degree(s): **M.D.** Title or Position: **Vice Chairman**

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

**3500 Fifth Avenue**

City: **Pittsburgh** State/Province: **PENNSYLVANIA** Zip/Postal Code: **15213**

Country (if outside the U.S.):

\*Phone: **412 383-1480** FAX: **412 383-1508** \*E-Mail: **aviva.katz@chp.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>
Katz, Aviva	M	M.D.	S	Child Psychiatry	Y	
Howrie, Denise	F	PharmD	S	Pharmacy	Y	
Venkataraman, Shekhar	M	MD	S	pediatric critical care medicine	Y	
Burke, Jeffrey	M	PhD	S	child psychology	Y	
Puhalla, Shannon	F	MD	S	hematology/oncolog y	Y	
Martin, Judith	F	MD	S	Pediatric Infectious Diseases	Y	
Greenaway, Patty	F	RN, BSN	S	oncology nursing	Y	
Katz, Aviva	F	MD	S	pediatric surgery	Y	
Szanto, Katalin	F	MD	S	psychiatry	Y	
Cornelius, Jack	M	MD, MPH	S	psychiatry, addiction medicine	Y	
Levine, Myriam	F	BA	N	non-scientist, retired teacher	N	
Shuman, Nancy	F	BBA	N	business	N	
Jain, Samay	M	MD, MS	S	neurology, movement disorders	Y	
Jill, Aubrecht	F	MBA, MSN, RN	S	MBA, MSN, RN	Y	
Huppert, Theodore	M	PhD	S	radiology, MR research	Y	
Jackson Graves, Carlyn	F	BS	N	study coordination, GCP	Y	
George, Betsy	F	RN, PhD	S	tertiary, critical care	Y	
Rubin, Joshua	M	MD	S	surgical oncology	Y	
Harter, Nancy	F	N/A	N	research administration	Y	
Handen, Benjamin	M	PhD	S	child psychology; autism	Y	
<b>Alternative Members</b>						
Holloway, Melanie	F	RN, BSN	S	pediatric nursing	Y	any other scientific memt
DeSantes, Lisa	F	BS	N	IRB regulations, study coordination	Y	any non-sci member
Hollabaugh, Kim	F	MSN, RN	S	nursing, critical care	Y	any other scientific memt
Wang, Norman	M	MD	S	cardiology, electrophysiology	Y	any physician member
Lantz, Susan	F	MDiv	N	pastoral care	N	any non-scientific membe

Lee, Ann	F	MSN, CRNP, CIP	S	cardiology, heart/lung transplant	Y	any other scientist
Doyle, William	M	PhD	S	pediatric otolaryngology	Y	prisoner representative, a scientific member
Shatzer, Melanie	F	DNP, RN	S	cardiothoracic nursing & nursing ed	Y	any other scientist
Gangopadhyay, Nupur	M	DVM, MS, PhD	S	immunology and virology	Y	any other scientific memt
Flickinger, John	M	MD	S	radiation oncology	Y	any physician member
Carey, Tom	M	MSW, CIP	S	social work, IRB regulations	Y	any other scientific memt

## NOTES:

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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: **IRB00004006**

(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):

**U of Pittsburgh IRB #8 - H**

C. Location of the IRB

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

**3500 Fifth Avenue  
Hieber Building**

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

\*City: **Pittsburgh**                      \*State/Province: **PENNSYLVANIA**      \*Zip/Postal Code: **15213**

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

\*Phone: **412 383-1480**      \*FAX: **412 383-1508**                      \*E-Mail: **miklosm@upmc.edu**

D. ♦Approximate number of full time equivalent positions devoted to the IRB's administrative activities: **20**

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): **7580**

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): **694**

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:

**283**

‡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: **Margaret** Middle Initial: \*Last Name: **Hsieh**

Earned Degree(s): **MD** Title or Position: **Chairman**

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

**3500 Fifth Avenue**

City: **Pittsburgh** State/Province: **PENNSYLVANIA** Zip/Postal Code: **15213**

Country (if outside the U.S.):

\*Phone: **412 383-1480** FAX: **412 383-1508** \*E-Mail: **hsiehm@upmc.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>
Hsieh, Margaret	F	MD	S	Emergency Medicine	Y	
Zorn, Kristin	F	MD	S	Gynecologic Oncology	Y	
Moses-Kolko, Eydie	F	MD	S	Behavioral Health; PET	Y	
Govil, Manika	F	PhD	S	craniofacial, statistical genetics	Y	
Pingpank, James	M	MD	S	surgical oncology	Y	
Hsieh, Margaret	F	MD	S	emergency medicine	Y	
Reiche, Teri	F	BS, CIP	N	IRB regulations	Y	
Brandom, Barbara	F	MD	S	Pediatric Anesthesiology	Y	
Watchko, Jon	M	MD	S	Newborn Medicine	Y	
Valenta, Cindy	F	RN, MSN, CNRN	S	Critical Care, Neuro, Trauma	Y	
Abt, John	M	PhD, ATC	S	sports medicine	Y	
Brach, Jennifer	F	PhD	S	physical therapy	Y	
Johnson, Bruce	M	MD	S	pulmonary, critical care medicine	Y	
Cornelius, Jack	M	MD, MPH	S	psychiatry, addiction medicine	Y	
Holloway, Melanie	F	RN, BSN, CIP	S	pediatric nursing	Y	
Schonder, Kristine	F	PharmD	S	pharmacy and therapeutics, transplant	Y	
Canavan, Timothy	M	MD	S	OB/Gyn; ultrasound	Y	
McGough, Richard	M	MD	S	orthopedic surgery	Y	
Phillips, Brandi	F	MSPPM	N	non-scientist; healthcare administration	N	
Knapp, Beth	F	MS	N	Non-scientific	N	
<b>Alternative Members</b>						
Seybert, Amy	F	PharmD	S	pharmacy and therapeutics	Y	any other scientific memt
DeSantes, Lisa	F	BS, CIP	N	IRB regulations	Y	any non-scientific membe
Hollabaugh, Kim	F	MSN, RN	S	nursing, critical care	Y	any other scientific memt
Greenaway, Patty	F	RN, BSN	S	oncology nursing	Y	any other scientific memt
Lee, Ann	F	MSN, CRNP,	S	cardiology, heart/lung	Y	any other scientific memt

**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?

[ X ] Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: **IRB00004728**

(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):

**IRB00004728 U of Pittsburgh IRB #9 – D**

C. Location of the IRB

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

**3500 Fifth Avenue  
Hieber Building**

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

\*City: **Pittsburgh**                      \*State/Province: **PENNSYLVANIA**      \*Zip/Postal Code: **15213**

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

\*Phone: **412 383-1480**      \*FAX: **412 383-1508**                      \*E-Mail: **miklosm@upmc.edu**

D. ♦Approximate number of full time equivalent positions devoted to the IRB's administrative activities: **20**

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): **7580**

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): **694**

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:

**283**

‡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: **Sue** Middle Initial: \*Last Name: **Beers**

Earned Degree(s): **PhD** Title or Position: **Chairman**

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

**3500 Fifth Avenue**

City: **Pittsburgh** State/Province: **PENNSYLVANIA** Zip/Postal Code: **15213**

Country (if outside the U.S.):

\*Phone: **412 383-1480** FAX: **412 383-1508** \*E-Mail: **beerssr@upmc.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>
Beers, Sue	F	PhD	S	pediatric neuropsychology	Y	
Gunawardena, Sriya	F	MD	S	Hematology/Oncology	Y	
Shaikh, Nader	M	MD	S	Pediatrics	Y	
Campbell, Susan	F	PhD	S	Psychology	Y	
Squires, Janet	F	MD	S	child abuse, pediatric infectious diseases	Y	
Beers, Sue	F	PhD	S	pediatric neuropsychology	Y	
Vieira, Alexandre	M	DDS, MS, PhD	S	genetics, dentistry	Y	
Doi, Yohei	M	MD, PhD	S	infectious diseases	Y	
Hollabaugh, Kim	F	MSN, RN, CIP	S	nursing	Y	
Choudry, M. Haroon	M	MD	S	surgical oncology	Y	
Cipkala-Gaffin, Jan	F	DrPh, MN, RN	S	nursing, mental health	Y	
Drappatz, Jan	M	MD	S	neuro-oncology, oncology	Y	
Pischke, Jack	M	MSW	N	incarceration	Y	prisoner representative
Finder, Jonathan	M	MD	S	pediatric pulmonology	Y	
Howrie, Denise	F	PharmD	S	pharmacy	Y	
Kolko, David	M	PhD	S	child & adolescent psychiatry	Y	
Mandel, Ellen	F	MD	S	pediatric otolaryngology	Y	
Scott, Nancy	F	BA	N	non-scientific; medical technology	Y	
Sperling, Mark	M	MD	S	Pediatrics, endocrinology	Y	
Kumer, Connie	F	MEd	N	non-scientist; public assistance	N	
Ryan, Robert	M	EdD	N	non-scientific, volunteer work	N	
<b>Alternative Members</b>						
Lee, Ann	F	MSN, CRNP, CIP	S	cardiology, heart/lung transplant	Y	any other scientific memt
DeSantes, Lisa	F	BS	N	IRB regulations, study	Y	any non-scientific membe

Doyle, William	M	PhD	S	coordination pediatric otolaryngology	Y	prisoner representative, a scientific member
Holloway, Melanie	F	RN, BSN, CIP	S	pediatric nursing, IRB regulations	Y	any other scientific memb

## 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.

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.*