Submission#: **105636**
IORG#: **IORG0000196**
Institution: **U of Pittsburgh**

OMB No. 0990-0279
Approved for use through October 31, 2018

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? 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: **George** Middle Initial: **A** *Last Name: **Huber**

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

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

Cathedral of Learning
4200 Fifth Avenue

*City: **Pittsburgh** *State/Province: **PENNSYLVANIA** *Zip/Postal Code: **15260**

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

*Phone: **412 624-5354** *FAX: **412 624-6903** *E-Mail: **ghuber@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: **Associate Director**

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: **mgm12@pitt.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: **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): **1284**

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): **143**

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: **40**

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

X	human drugs	food additives
X	medical devices	color additives
X	biological	other
		Specify:

H. IRB Chairperson

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

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

Mailing Address (if different from the Mailing Address in section 3):
3500 Fifth Avenue, Suite 106

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: **judy.martin@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.

Member Name (Last, First)	Sex M/F	Earned Degree(s)	Scientist (S) Non-scientist (N)	Primary Scientific or Non-Scientific Specialty	Affiliation with Institution(s) Y/N	Comments
Martin, Judith	M	MD	S	OB/GYN	Y	
Dilts, Robert	M	PhD	N	Mathematics	Y	
Howland, Robert	M	MD	S	Psychiatry	Y	
Mitchell-O'Brien, Leeann	F	JD	N	Health and Hospital Law	N	
Soran, Ozlem	F	MD	S	Cardiology	Y	
Irrgang, James	M	PhD, PT, ATC	S	Orthopedics, PT, Rehabilitation	Y	
Schwartz, Miriam	F	none	N	support groups	N	
Manders, Ernest	M	MD	S	plastic & reconstructive surgery	Y	
Summersgill, Kurt	M	DDS, PhD	S	dental medicine, pathology	Y	
Raman, Venkataramanan	M	PhD	S	pharmacy	Y	
Yip, Lin	F	MD	S	surgical oncology, endocrine surgery	Y	
Corcoran, Timothy	M	PhD	S	drug development, nuclear imaging	Y	
Hoffman, Rose	F	PhD, RN	S	nursing, acute and tertiary care	Y	
Spillane, Susan	F	RN, CCRP	S	nursing, research coordination	Y	

Alternative Members

Orndoff, Patricia	F	RN, MEd	S	Nursing	Y	any other scientific member
DeSantes, Lisa	F	BS, CIP	N	IRB regulations, study coordination	Y	any non-scientific member
Comerci, John	M	MD	S	oncology, gynecology	Y	any physician member
Appleman, Leonard	M	MD	S	hematology/oncology	Y	any physician member
Gerger, Allison	F	MPH	S	research coordinator, international	Y	any other scientific member
DiVirgilio, Dana	F	MPH	S	community health, study coordination	Y	any other scientist
Fuhrman, Amy	F	MPA	N	research coordination	Y	any non-scientific member
Valenti, Shannon	F	BS, MBA	N	Research regulations	Y	any non-scientific member
Miklos, Melissa	F	BS, CIP	N	IRB regulations	Y	any non-scientific member
Carey, Thomas	M	MSW, CIP	S	Social Work, IRB regulations	Y	any other scientist
Brufsky, Adam	M	MD, PhD	S	Hematology/Oncology	Y	any physician member

Wenzel, Sally	F	MD	S	Pulmonary, Allergy & Critical Care Medic	Y	any physician member
Moss, Deborah	F	MD	S	pediatrics	Y	any physician member
Hurst, Kathleen	F	N/A	N	administrative	Y	any non-scientific member
Ivanusic, Carolyn	F	BS, MSW	N	IRB regulations	Y	any non-scientific member
Grabowski, Erin	F	BS, CIP	N	IRB regulations, psychology	Y	any non-scientific member
LeMenager, Michelle	F	BS	N	IRB regulations	Y	any non-scientific member
Navratil, Judith	F	BA	N	IRB regulations	Y	any non-scientific member
Guido, Richard	M	MD	S	OB/GYN	Y	University of Pittsburgh IRB Executive Chairman
McKaveney, Theresa	F	BS	N	IRB regulations	Y	any non-scientific member
Wei, Lawrence	M	MD	S	cardiothoracic surgery	Y	any physician member
Hollabaugh, Kim	F	MSN, RN	S	nursing	Y	any other scientist
Lee, Ann	F	MSN, CRNP, CIP	S	cardiology, heart/lung transplant	Y	any other scientific member
Holloway, Melanie	F	RN, BSN	S	pediatric nursing	Y	any other scientist
Landolina, Nicholas	M	MPM, M.Ed.	N	management, non-scientific	Y	any non-scientific 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 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: **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: **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): **1284**

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): **143**

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: **40**

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

X	human drugs	food additives
X	medical devices	color additives
X	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.

Member Name (Last, First)	Sex M/F	Earned Degree(s)	Scientist (S) Non-scientist (N)	Primary Scientific or Non-Scientific Specialty	Affiliation with Institution(s) Y/N	Comments
Hsieh, Margaret	F	MD	S	Emergency Medicine	Y	
Palmer, Catherine	F	PhD	S	Audiology	Y	
Schraut, Wolfgang	M	MD	S	Surgery	Y	
Chang, Judy	F	MD, MPH	S	OB/Gyn	Y	
Weyant, Donna	F	MSN, RN, CPN	S	pediatric nursing	Y	
Hathaway, Bridget	F	MD	S	otolaryngology	Y	
VanSwearingen, Jessie	F	PhD	S	physical therapy	Y	
Hrynkiw, Nancy	F	BS	N	non-scientific community member	N	
Jonkman, Lauren	F	PharmD, MPH, BCPS	S	Pharmacy and therapeutics	Y	
Holloway, Melanie	F	RN, BSN, CIP	S	pediatric nursing	Y	
Barnato, Amber	F	MD, MPH, MS	S	preventive medicine	Y	
Jackson Graves, Carlyn	F	BS	N	study coordination, GCP	Y	
Michel, Ian	M	JD	N	legal	Y	
Spiess, Alex	M	MD	S	orthopedics, plastic surgery, hand	Y	
Pischke, Jack	M	MSW	N	incarceration, social work, advocacy	Y	prisoner representative

Alternative Members

Gingrich, Jeffrey	M	MD	S	Urology	Y	any physician member
Becker, Stacey	F	BS	S	cognitive psychology; Autism-Neurobiolog	Y	any other scientist
Lee, Ann	F	MSN, RN, CRNP, CIP	S	cardiology, heart/lung tx	Y	any other scientific member
Davis, Jan	F	RN, PhD, CRNP	S	cardiopulmonary nursing	Y	
DeSantes, Lisa	F	BS, CIP	N	IRB regulations, study coordination	Y	any non-scientific member
Engh, Johnathan	M	MD	S	Neurological surgery	Y	any other physician member
Libman, Ingrid	F	MD, PhD	S	pediatric endocrinology	Y	any physician member
Spillane, Susan	F	RN, CCRP	S	nursing, research coordination	Y	any other scientific member
Carey, Tom	M	MSW, CIP	S	Social work, IRB regulations	Y	any other scientific member
Houston, Neil	M	BA	N	medical student	Y	any non-scientific 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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[X] Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: **IRB00000321**

(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 #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: **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): **1284**

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): **143**

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: **40**

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

X	human drugs	food additives
X	medical devices	color additives
X	biological	other
		Specify:

H. IRB Chairperson

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

Earned Degree(s): **MD** Title or Position: **Vice 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: **judy.martin@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.

Member Name (Last, First)	Sex M/F	Earned Degree(s)	Scientist (S) Non-scientist (N)	Primary Scientific or Non-Scientific Specialty	Affiliation with Institution(s) Y/N	Comments
Martin, Judith	M	MD	S	OB/Gyn	Y	
Doi, Yohei	M	MD, PhD	S	infectious diseases	Y	
Hilmi, Ibtesam	F	MBCHB, FRCA	S	anesthesia	Y	
Carey, Thomas	M	MSW	S	social work, IRB regulations	Y	
Harter, Nancy	F	n/a	N	research administration	Y	
Miller, Barbara	F	BS, MS	S	ophthalmology research	Y	
Gildengers, Ariel	M	MD	S	psychiatry	Y	
George, Betsy	F	RN, PhD	S	tertiary, critical care	Y	
Yanowitz, Toby	F	MD	S	neonatology, pediatrics	Y	
Hoffman, Paul	M	BS, RPh	S	pharmacy	Y	
Cipkala-Gaffin, Jan	F	DrPh, MN, RN	S	nursing, PCOS, mental health	Y	
Hurst, Daniel	M	M.Div.	N	medical ethics, informed consent	N	
Prasad, Konasale	M	MD	S	psychiatry, genetics	Y	
Johnson, Amy	F	RPh	S	pharmacy, IDS	Y	
Suryawanshi, Swati	F	PhD	S	cellular biology, microbiology, uro-gyn	Y	
Brufsky, Adam	M	MD, PhD	S	hematology/oncology	Y	
Alternative Members						
Holloway, Melanie	F	RN, BSN, CIP	S	pediatric nursing, IRB regulations	Y	any other scientific member
Schuchert, Matt	M	MD	S	Thoracic Surgery	Y	any other physician
Irrgang, James	M	PhD, PT, ATC	S	orthopaedics, PT, rehab	Y	any other scientific member
Pischke, Jack	M	MSW	N	incarceration	Y	prisoner representative, any non-scientist
Hollabaugh, Kim	F	MSN, RN, CIP	S	nursing	Y	any other scientist
DeSantes, Lisa	F	BS, CIP	N	IRB regulations	Y	any non-scientist
Lee, Ann	F	MSN, CRNP, CIP	S	cardiology, heart/lung transplant	Y	any other scientist
Miklos, Melissa	F	BS, CIP	N	IRB regulations	Y	any non-scientific member
Barone, Jean	F	CIP	N	IRB regulations	Y	any non-scientist

Hsieh, Margaret	F	MD	S	Emergency Medicine	Y	any physician member
Oliver, D. Lamar	M	BS	N	electrical engineering, non-scientist	N	any non-scientist
Zelazny, Jamie	F	RN, MPH	S	psychiatric nursing	Y	any other scientific member
Chang, Judy	F	MD, MPH	S	OB/GYN	Y	any physician member
Venkataraman, Shekhar	M	MD	S	pediatric critical care	Y	any physician member

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: **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: **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): **1284**

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): **143**

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: **40**

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

X	human drugs	food additives
X	medical devices	color additives
X	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.

Member Name (Last, First)	**Sex M/F**	**Earned Degree(s)**	**Scientist (S) Non-scientist (N)**	**Primary Scientific or Non-Scientific Specialty**	**Affiliation with Institution(s) Y/N**	**Comments**
Guido, Richard	M	M.D.	S	OB/GYN	Y	
Hsieh, Margaret	F	MD	S	Emergency Medicine	Y	
Barone, Jean	F	CIP	N	IRB regulations	Y	
Beers, Susan	F	PhD	S	Pediatric neuropsychology	Y	
Sweet, Robert	M	MD	S	psychiatry	Y	
Zelazny, Jamie	F	MPH, RN	S	psychiatric nursing	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	
Martin, Judith	F	MD	S	pediatric infectious disease	Y	
Alternative Members						
Horwitz, Mara	F	MD	S	medicine, endocrinology	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 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: **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: **3**

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): **1285**

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 **143**

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: **40**

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

X	human drugs	food additives
X	medical devices	color additives
X	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.

Member Name (Last, First)	Sex M/F	Earned Degree(s)	Scientist (S) Non-scientist (N)	Primary Scientific or Non-Scientific Specialty	Affiliation with Institution(s) Y/N	Comments
Katz, Aviva	M	M.D.	S	Child Psychiatry	Y	
Handen, Benjamin	M	PhD	S	child psychology; autism	Y	
Rubin, Joshua	M	MD	S	surgical oncology	Y	
Olawaiye, Alexander	M	MD	S	OB/GYN, oncology	Y	
Fowler, John	M	MD	S	orthopedic surgery	Y	
Ziobert, Staci	F	PharmD	S	pharmacy	Y	
Holliman, Jennifer	F	MPA	N	community outreach	N	
Parikh, Rahul	M	MBBS, PhD	S	medical oncology, internal medicine	Y	
Ho, Ken	M	MD, MPH	S	Infectious Diseases	Y	
Huppert, Theodore	M	PhD	S	radiology, MR research	Y	
Puhalla, Shannon	F	MD	S	hematology/oncolog y	Y	
Lee, Ann	F	MSN, CRNP, CIP	S	cardiology, heart/lung transplant	Y	
Jain, Samay	M	MD, MS	S	neurology, movement disoriders	Y	
Howrie, Denise	F	PharmD	S	Pharmacy	Y	
Venkataraman, Shekhar	M	MD	S	pediatric critical care medicine	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	

Alternative Members

Jack, Pischke	M	MSW	N	incarceration, prisoner representative	Y	prisoner rep
Spillane, Susan	F	RN, CCRP	S	nursing, research coordination	Y	any other scientist
Holloway, Melanie	F	RN, BSN	S	pediatric nursing	Y	any other scientific member
Doyle, William	M	PhD	S	pediatric otolaryngology	Y	prisoner representative, any other scientific member
DeSantes, Lisa	F	BS	N	IRB regulations, study coordination	Y	any non-scientific member
Hollabaugh, Kim	F	MSN, RN	S	nursing, critical care	Y	any other scientific member
Wang, Norman	M	MD	S	cardiology,	Y	any physician member

				electrophysiology		
Carey, Tom	M	MSW, CIP	S	social work, IRB regulations	Y	any other scientific 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 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: **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: **3**

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): **1285**

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): **144**

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: **41**

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

X	human drugs	food additives
X	medical devices	color additives
X	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.

Member Name (Last, First)	Sex M/F	Earned Degree(s)	Scientist (S) Non-scientist (N)	Primary Scientific or Non-Scientific Specialty	Affiliation with Institution(s) Y/N	Comments
Hsieh, Margaret	F	MD	S	Emergency Medicine	Y	
Govil, Manika	F	PhD	S	craniofacial, statistical genetics	Y	
Pingpank, James	M	MD	S	surgical oncology	Y	
Phillips, Brandi	F	MSPPM	N	non-scientist; healthcare administration	N	
Knapp, Beth	F	MS	N	Non-scientific	N	
McGough, Richard	M	MD	S	orthopedic surgery	Y	
Watchko, Jon	M	MD	S	Newborn Medicine	Y	
Brandom, Barbara	F	MD	S	Pediatric Anesthesiology	Y	
Reiche, Teri	F	BS, CIP	N	IRB regulations	Y	
Valenta, Cindy	F	RN, MSN, CNRN	S	Critical Care, Neuro, Trauma	Y	
Cornelius, Jack	M	MD, MPH	S	psychiatry, addiction medicine	Y	
DeSantes, Lisa	F	BS, CIP	N	IRB regulations	Y	
Conner, Ian	M	MD, PhD	S	ophthalmology	Y	
Johnson, Bruce	M	MD	S	pulmonary, critical care medicine	Y	

Alternative Members

Holloway, Melanie	F	RN, BSN, CIP	S	pediatric nursing	Y	any other scientist
Brach, Jennifer	F	PhD	S	physcial therapy	Y	any other scientific member
Lee, Ann	F	MSN, CRNP, CIP	S	cardiology, heart/lung transplant	Y	any other scientific member
Carey, Tom	M	MSW, CIP	S	social work, IRB regulations	Y	any other scientist
Seybert, Amy	F	PharmD	S	pharmacy and therapeutics	Y	any other scientific 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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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: **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): **1285**

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): **144**

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: **41**

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

X	human drugs	food additives
X	medical devices	color additives
X	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.

Member Name (Last, First)	Sex M/F	Earned Degree(s)	Scientist (S) Non-scientist (N)	Primary Scientific or Non-Scientific Specialty	Affiliation with Institution(s) Y/N	Comments
Beers, Sue	F	PhD	S	pediatric neuropsychology	Y	
Shaikh, Nader	M	MD	S	Pediatrics	Y	
Vieira, Alexandre	M	DDS, MS, PhD	S	genetics, dentistry	Y	
Kumer, Connie	F	MEd	N	non-scientist; public assistance	N	
Kolko, David	M	PhD	S	child & adolescent psychiatry	Y	
Howrie, Denise	F	PharmD	S	pharmacy	Y	
Finder, Jonathan	M	MD	S	pediatric pulmonology	Y	
Mandel, Ellen	F	MD	S	pediatric otolaryngology	Y	
Drappatz, Jan	M	MD	S	neuro-oncology, oncology	Y	
Pasek, Tracy	F	RN, MSN	S	Pediatric ICU nursing	Y	
Choudry, M. Haroon	M	MD	S	surgical oncology	Y	
Ryan, Robert	M	EdD	N	education administration	Y	
Pischke, Jack	M	MSW	N	incarceration	Y	prisoner representative
Squires, Janet	F	MD	S	child abuse, pediatric infectious diseas	Y	
Holloway, Melanie	F	RN, BSN, CIP	S	pediatric nursing, IRB regulations	Y	any other scientific member

Alternative Members

Doyle, William	M	PhD	S	pediatric otolaryngology	Y	prisoner representative, any other scientific member
Lee, Ann	F	MSN, CRNP, CIP	S	cardiology, heart/lung transplant	Y	any other scientific member
DeSantes, Lisa	F	BS	N	IRB regulations, study coordination	Y	any non-scientist
Hollabaugh, Kim	F	MSN, RN, CIP	S	nursing	Y	any other scientific member
Carey, Thomas	M	MSW	S	social work, IRB regulations	Y	any other scientific member
Spillane, Susan	F	RN, CCRP	S	nursing, research coordination	Y	any other scientific 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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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.*