

IORG #: **IORG0000135**
Institution: **University of California, San Francisco**
Expires: **02/14/2027**

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

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

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

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

This form is to be used for the following purposes:

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

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

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

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

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

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

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

- 2. *What is your institution or organization (IORG) number? IORG0000135**

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: **University of California, San Francisco**

*Mailing Address: **Human Research Protection Program
490 Illinois Street
Floor 6
San Francisco, CA 94158**

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

*City: **San Francisco** *State/Province: **CALIFORNIA** *Zip/Postal Code: **94158**

*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: **Brian**

Middle Initial:

*Last Name: **Smith**

Earned Degree(s): **JD, MBA**

Title or Position:

**Chief Ethics and Compliance
Officer/Sr Assoc Vice Chancellor -
Research**

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

**Office of Research
490 Illinois Street
Room 51Q
UCSF Office of Research**

*City: **San Francisco**

*State/Province: **CALIFORNIA**

*Zip/Postal Code: **94143-0294**

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

*Phone: **415 502-3468**

*FAX: **415 476-4099**

*E-Mail: **brian.smith@ucsf.edu**

5. Contact Person Providing this Registration Information

*First Name: **Edward**

Middle Initial:

*Last Name: **Kuczynski**

Earned Degree(s): **MA**

Title or Position:

**Director, Human Research
Protection Program**

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

University of California, San Francisco (UCSF)

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

**Human Research Protection Program
490 Illinois Street
Floor 6
San Francisco, CA 94158**

*City: **San Francisco** *State/Province: **CALIFORNIA** *Zip/Postal Code: **94158**
*Country (if outside the
*Phone: **415 415-9246** *FAX: **415 502-1347** *E-Mail: **edward.kuczynski@
ucsf.edu**

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

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

Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: **IRB00000229**

(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):

Parnassus Committee IRB #1

C. Location of the IRB

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

**Human Research Protection Program
490 Illinois Street
Floor 6
San Francisco, CA 94158**

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

*City: **San Francisco** *State/Province: **CALIFORNIA** *Zip/Postal Code: **94158**

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

*Phone: **415 476-1814** *FAX: **415 353-4418** *E-Mail: **irb@ucsf.edu**

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

5

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):

930

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):

246

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:

322

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

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

H. IRB Chairperson

*First Name: **Victor** Middle Initial: *Last Name: **Reus**

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

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

Human Research Protection Program

490 Illinois Street

Floor 6

San Francisco, CA 94158

City: **San Francisco** State/Province: **CALIFORNIA** Zip/Postal Code: **94158**

Country (if outside the U.S.):

*Phone: **415 476-1814** FAX: **415 353-4418** *E-Mail: **Victor.Reus@ucsf.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
Reus, Victor	M	MD	S	Psychiatry	Y	Primary Member (Chair)
Viele, Carol	F	RN, MS, CNS	S	Hematology/Oncology	Y	Primary Member (Vice Chair)
Posselt, Andrew	M	MD, PhD, FACS	S	Surgery, Bariatric and Transplant	Y	Primary Member
Meadows, Jeffery	M	MD	S	Pediatrics, Cardiology	Y	Primary Member
Banerjee, Anuradha	F	MD	S	Pediatrics and Neurological Surgery	Y	Primary Member
Deol, John-Paul	M	JD	N	Employment Law/Health Policy	N	Primary Member (Community Member)
Hernandez Pampaloni, Jose	M	MD, PhD	S	Radiology	Y	Primary Member
Cohen, Beth	F	MD, MAS	S	Medicine	Y	Primary Member (SFVAHCS representative)
Lee, Chanhung	F	MD, PhD	S	Anesthesia, Neurosurgical anesthesia	Y	Primary Member
Singh, Vineeta	F	MD	S	Critical Care and Vascular Neurology	Y	Primary Member
Cheng, Judy	F	MD, PhD	S	Hematology/Oncology	Y	Primary Member
Lobo, Errol	M	MD	S	Anesthesia and Perioperative Care	Y	Primary Member (Vice Chair)
Alternative Members						
Bersot, Thomas P.	M	MD, PhD	S	Cardiovascular Disease	Y	Alternate for all Scientists (S)
Jones, Reese	M	MD	S	Psychiatry, Drug Dependence	Y	Alternate for all Scientists (S)
Wara, Diane W.	F	MD	S	Pediatrics, HIV/AIDS, Immunology	Y	Alternate for all Scientists (S)
Tioupine, Liz	F	BS, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Chao, Karen	F	BS, PhD, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Fung, Gordon	M	MD, MPH, PhD	S	Cardiology	Y	Alternate for all Scientists (S)

Libke, Robert	M	MD	S	Infectious Diseases, Internal Medicine	Y	Alternate for all Scientists (S)
Katz, Patricia	F	PhD	S	Outcomes Research, Psychosocial Issues	Y	Alternate for all Scientists (S)
Mickalian, Joanne	F	MA, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Tulsky, Jacqueline P.	F	MD	S	Internal Medicine, HIV	Y	Alternate for all Scientists (S)
Etter, Cheri	F	BS, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Keenan, Jason	M	MS, CIP	S	Regulatory Science	Y	Alternate for all Scientists (S)
Nolan, Kathryn	F	MPH, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Phillips, Jessica	F	BA	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Simpkins, Karen	F	MLS	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Goldberger, Wendy	F	MS	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Denis, Randy	M	MSN, CIP	S	Nursing	Y	Alternate for all Scientists (S)
Din, Imad	M	BS	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Grosvenor, Jonathan	M	CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Hagan-Colyar, T aylar	F	BS, CIP, CHES	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Vargas, Iya	F	BS	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Leslie, Kieron	M	MBBS, MD	S	Dermatology	Y	Alternate for all Scientists (S)
Martin, Thomas	M	MD	S	Medicine	Y	Alternate for all Scientists (S)
Quivey, Jeanne	F	MD	S	Radiation Oncology	Y	Alternate for all Scientists (S)
Warren, Robert	M	MD	S	Surgery	Y	Alternate for all Scientists (S)
Koger-Hunt, Janae	F	MA	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Venook, Alan	M	MD	S	Hematology/Onc	Y	Alternate for all Scientists (S)
Michlitsch, Jennifer	F	MD	S	Pediatric Hem/Oncology	Y	Alternate for all Scientists (S)
D'Harlingue, Arthur	M	MD	S	Neonatology	Y	Alternate for all Scientists

							(S)
Stinson, Joel	M	CIP	N	HRPP Admin	Y		Alternate for non-scientist (NS)
Henderson, Susanne	F	RN	S	Nursing	Y		Alternate for all Scientists (S)
Patel, Ami	F	MPH	N	HRPP Admin	Y		Alternate for non-scientist (NS)
Coons, Erin	F	MCR, CIP, RAC	N	HRPP Admin	Y		Alternate for non-scientist (NS)
Meyer, Kelsey	F	MA	N	HRPP Admin	Y		Alternate for non-scientist (NS)
Swearingen, William	M	JD	N	HRPP Admin	Y		Alternate for non-scientist (NS)
Okumura, Megumi	F	MD, MAS	S	Pediatrics	Y		Alternate for all Scientists (S)
Feaman, Sara	F	MS, CCRP	S	Applied Analytics	Y		Alternate for all Scientists (S)
Heredia, Alejandro	M	MA	N	HRPP Admin	Y		Alternate for non-scientists (NS)
Teran, Angie	F	MA	N	HRPP Admin	Y		Alternate for non-scientists (NS)
Hancer, Lana	F	MPH, CIP	N	HRPP Admin	Y		Alternate for non-scientists (NS)
Velez, Mario	M	AA	N	HRPP Admin	Y		Alternate for non-scientists (NS)
Hildebrandt, Isabel	F	PhD, CIP	S	AI	Y		Alternate for all Scientists (S)
Bugatto, Annette	F	BA, CIP	N	HRPP Admin	Y		Alternate for non-scientists (NS)
Tabbutt, Sarah	F	MD, PhD	S	Pediatrics	Y		Alternate for all Scientists (S)
Daud, Adil	M	MD	S	Hematology/Oncology; Melanoma	Y		Alternate for all Scientists (S)
Donnelly, Sarah	F	MA, CIP	N	HRPP Admin	Y		Alternate for non-scientists (NS)
Irwin, Beth	F	MA, LPC, CIP	N	HRPP Admin	Y		Alternate for non-scientists (NS)

NOTES:

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

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

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

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

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

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

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

Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: **IRB00000230**

(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):

San Francisco General Hosp (SFGH) Committee IRB #2

C. Location of the IRB

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

**Human Research Protection Program
490 Illinois Street
Floor 6
San Francisco, CA 94158**

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

*City: **San Francisco** *State/Province: **CALIFORNIA** *Zip/Postal Code: **94158**

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

*Phone: **415 476-1814** *FAX: **415 353-4418** *E-Mail: **irb@ucsf.edu**

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

5

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):

923

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):

415

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:

292

‡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: **Thomas** Middle Initial: *Last Name: **Bersot**

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

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

Human Research Protection Program

490 Illinois Street

Floor 6

San Francisco, CA 94158

City: **San Francisco** State/Province: **CALIFORNIA** Zip/Postal Code: **94158**

Country (if outside the U.S.):

*Phone: **415 476-1814** FAX: **415 353-4418** *E-Mail: **tbersot@gladstone.ucsf.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
Bersot, Thomas	M	MD	S	Cardiovascular disease	Y	Primary Member (Chair)
Tulsky, Jacqueline P.	F	MD	S	Internal Medicine, HIV	Y	Primary Member (Vice Chair)
Leslie, Kieron	M	MD	S	Dermatology	Y	Primary Member (Vice Chair)
Fisher-Owens, Susan	F	MD, MPH	S	Pediatrics	Y	Primary Member
Lindan, Christina P.	F	MD, MS	S	Epidemiology and Biostatistics	Y	Primary Member
Coffin, Phillip	M	MD, MIA	S	Substance Use / HIV	N	Primary Member (SFDPH representative)
Miller, Christina	F	BSN	N	Community Member	N	Primary Member (Community Member)
Strigo, Irina	F	PhD	S	Neuroimaing/Pain/P sychopathology	Y	Primary Member (SFVAHCS representative)
Martin, Holly	F	MD	S	Pediatrics	Y	Primary Member
Phillips, Patrick	M	PhD, MS, MA	S	Medicine	Y	Primary Member
Farrant, Mary	F	MBA, RN, BSN, PHN	S	Neurology	Y	Primary Member
Alternative Members						
Jones, Reese	M	MD	S	Psychiatry, Drug Dependence	Y	Alternate for all Scientists (S)
Wara, Diane W.	F	MD	S	Pediatrics, HIV/AIDS, Immunology	Y	Alternate for all Scientists (S)
Chao, Karen	F	BS, PhD, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Fung, Gordon	M	MD, PhD, MPH	S	Cardiology	Y	Alternate for all Scientists (S)
Katz, Patricia	F	PhD	S	Outcomes Research/Psychosoc ial Issues	Y	Alternate for all Scientists (S)
Bugatto, Annette	F	BA, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Mickalian, Joanne	F	MA, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Viele, Carol	F	RN, MS, CNS	S	Hematology/Oncolo gy	Y	Alternate for all Scientists (S)

Fischer, Aaron	M	JD	N	Prisoner Representative	N	Alternate for non-scientists (NS)/Prisoner Representative
Etter, Cheri	F	BS, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Keenan, Jason	M	MS, CIP	S	Regulatory Science	Y	Alternate for all Scientists (S)
Nolan, Kathryn	F	MPH, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Phillip, Jessica	F	BA	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Simpkins, Karen	F	MLS	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Goldberger, Wendy	F	MS	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Chao, Linda	F	PhD	S	Radiology	Y	Alternate for all Scientists (S)/SFVAHCS Representative
Lynch, Megan	F	MS	N	Prisoner Advocate	Y	Alternate for non-scientists (NS)/Prisoner Representative
Kirsch, Heidi	F	MD	S	Neurology	Y	Alternate for all Scientists (S)
Denis, Randy	M	MSN, CIP	S	Nursing	Y	Alternate for all Scientists (S)
Din, Imad	M	BS	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Liu, Albert	M	MD, MPH	S	Medicine, HIV, SFDPH	Y	Alternate for all Scientists (S)
Lobo, Errol	M	MD, PhD	S	Anesthesia and Perioperative Care	Y	Alternate for all Scientists (S)
Reus, Victor	M	MD	S	Psychiatry	Y	Alternate for all Scientists (S)
Warren, Robert	M	MD	S	Surgery	Y	Alternate for all Scientists (S)
Grosvenor, Jonathan	M	CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Hagan-Colyar, Taylar	F	BS, CIP, CHES	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Philips, Jessica	F	BA	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Tioupine, Elizabeth	F	BS, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Vargas, Iya	F	BS	N	HRPP Admin	Y	Alternate for non-scientist (NS)

D'Harlingue, Arthur	M	MD	S	Neonatology	Y	Alternate for all Scientists (S)
Kornblith, Lucy	F	MD, FACS	S	Trauma Surgery	Y	Alternate for all Scientists (S)
Koger-Hunt, Janae	F	MA	S	HRPP Admin	Y	Alternate for non-scientist (NS)
Stinson, Joel	M	CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Michlitsch, Jennifer	F	MD	S	Pediatric Hem/Oncology	Y	Alternate for all Scientists (S)
Venook, Alan	M	MD	S	Hematology/Onc	Y	Alternate for all Scientists (S)
Henderson, Susanne	F	RN	S	Nursing	Y	Alternates for all Scientist (S)
Patel, Ami	F	MPH	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Coons, Erin	F	MCR, CIP, RAC	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Meyer, Kelsey	F	MA	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Swearingen, William	M	JD	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Okumura, Megumi	F	MD, MAS	S	Pediatrics	Y	Alternate for all Scientists (S)
Feaman, Sara	F	MS, CCRP	S	Applied Analytics	Y	Alternate for all Scientists (S)
Heredia, Alejandro	M	MA	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Teran, Angie	F	MA	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Hancer, Lana	F	MPH, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Velez, Mario	M	AA	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Hildebrandt, Isabel	F	PhD, CIP	S	AI	Y	Alternate for all Scientists (S)
Tabbutt, Sarah	F	MD, PhD	S	Pediatrics	Y	Alternate for all Scientists (S)
Daud, Adil	M	MD	S	Hematology/Oncology; Melanoma	Y	Alternate for all Scientists (S)
Donnelly, Sarah	F	MA, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Irwin, Beth	F	MA, LPC, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)

NOTES:

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

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

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

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

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

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

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

Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: **IRB00003471**

(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):

Laurel Heights Committee(Lhts) IRB #3

C. Location of the IRB

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

**Human Research Protection Program
490 Illinois Street
Floor 6
San Francisco, CA 94158**

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

*City: **San Francisco** *State/Province: **CALIFORNIA** *Zip/Postal Code: **94158**

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

*Phone: **415 476-1814** *FAX: **415 353-4418** *E-Mail: **irb@ucsf.edu**

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

5

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):

903

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):

354

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:

298

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

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

H. IRB Chairperson

*First Name: **Reese** Middle Initial: *Last Name: **Jones**

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

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

Human Research Protection Program

490 Illinois Street

Floor 6

San Francisco, CA 94158

City: **San Francisco** State/Province: **CALIFORNIA** Zip/Postal Code: **94158**

Country (if outside the U.S.):

*Phone: **415 476-1814** FAX: **415 353-4418** *E-Mail: **Reese.Jones@ucsf.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
Jones, Reese	M	MD	S	Psychiatry, Drug Dependence	Y	Primary Member (Chair)
Katz, Patricia	F	PhD	S	Outcomes research, psychosocial issues	Y	Primary Member (Vice Chair)
Wara, Diane W.	F	MD	S	Pediatrics, HIV/AIDS, Immunology	Y	Primary Member (Vice Chair)
Walsh- Cassidy, Judith	F	MD, MPH	S	Gen'l Internal Med/Women's Hlth	Y	Primary Member
Boyer, Cherrie	F	PhD	S	Pediatrics	Y	Primary Member
Detz, Clifford M.	M	PhD	N	Chemical physics	N	Primary Member (Community Member)
Behrends, Matthias	M	MD	S	Anesthesia & Perioperative Care	Y	Primary Member
Marmor, Meir	M	MD	S	Orthopaedic Surgery	Y	Primary Member
Grossman, Daniel	M	MD, FACOG	S	Gynecology & Reproductive Sciences	Y	Primary Member
Arjomandi, Merhdad	M	MD	S	VA Medicine -- Pulmonary, Critical Care	Y	Primary Member (SFVAHCS Representative)
Ziegler, David	M	PhD	S	Neurology	Y	Primary Member
Connelly, Stephen Thad	M	DDS, MD, PhD	S	Dentistry	Y	Primary Member
Creasman, Jennifer M.	F	MSPH	S	Informatics and research compliance	Y	Primary Member

Alternative Members

Bersot, Thomas P.	M	MD, PhD	S	Cardiovascular Disease	Y	Alternate for all Scientists (S)
Reus, Victor	M	MD	S	Psychiatry	Y	Alternate for all Scientists (S)
Chao, Karen	F	BS, PhD, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Tioupine, Liz	F	BS, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Fung, Gordon	M	MD, PhD, MPH	S	Cardiology	Y	Alternate for all Scientists (S)
Bugatto, Annette	F	BA, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)

Mickalian, Joanne	F	MA, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Viele, Carol	F	RN, MS, CNS	S	Hematology/Oncology	Y	Alternate for all Scientists (S)
Tulsky, Jacqueline P.	F	MD	S	Internal Medicine, HIV	Y	Alternate for all Scientists (S)
Bruhn, Roberta L.	F	PhD	S	BSRI	Y	Alternate for all Scientists (S)
Etter, Cheri	F	BS, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Keenan, Jason	M	MS, CIP	S	Regulatory Science	Y	Alternate for all Scientists (S)
Nolan, Katherine	F	MPH, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Phillips, Jessica	F	BA	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Simpkins, Karen	F	MLS	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Goldberger, Wendy	F	MS	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Tabbutt, Sarah	F	MD, PhD	S	Pediatrics	Y	Alternate for all Scientists (S)
Denis, Randy	M	MSN, CIP	S	Nursing	Y	Alternate for all Scientists (S)
Din, Imad	M	BS	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Kuo, Alfred	M	MD, PhD	S	Orthopaedic Surgery	Y	Alternate for all Scientists (S)/SFVAHCS Representative
Lobo, Errol	M	MD, PhD	S	Anesthesia and Perioperative Care	Y	Alternate for all Scientists (S)
Schallhorn, Julie	F	MD, MS	S	Ophthalmology	Y	Alternate for all Scientists (S)/SFVAHCS Representative
Vargas, Iya	F	BS	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Grosvenor, Jonathan	M	CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Hagan-Colyar, Taylar	F	BS, CIP, CHES	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Koger-Hunt, Janae	F	MA	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Sun, Catherine	F	MD	S	Ophthalmology	Y	Alternate for all Scientists (S)

Michlitsch, Jennifer	F	MD	S	Pediatric Hem/Oncology	Y	Alternate for all Scientists (S)
D'Harlingue, Arthur	M	MD	S	Neonatology	Y	Alternate for all Scientists (S)
Venook, Alan	M	MD	S	Hematology/Onc	Y	Alternate for all Scientists (S)
Henderson, Susanne	F	RN	S	Nursing	Y	Alternate for all Scientists (S)
Patel, Ami	F	MPH	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Coons, Erin	F	MCR, CIP, RAC	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Meyer, Kelsey	F	MA	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Swearingen, William	M	JD	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Okumura, Megumi	F	MD, MAS	S	Pediatrics	Y	Alternate for all Scientists (S)
Feaman, Sara	F	MS, CCRP	S	Applied Analytics	Y	Alternate for all Scientists (S)
Heredia, Alejandro	M	MA	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Teran, Angie	F	MA	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Hancer, Lana	F	MPH, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Velez, Mario	M	AA	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Hildebrandt, Isabel	F	PhD, CIP	S	AI	Y	Alternate for all Scientists (S)
Daud, Adil	M	MD	S	Hematology/Oncology; Melanoma	Y	Alternate for all Scientists (S)
Donnelly, Sarah	F	MA, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Irwin, Beth	F	MA, LPC, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)

NOTES:

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

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

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

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

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

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

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

Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: **IRB00005096**

(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 California San Francisco IRB #4 - Mt. Zion

C. Location of the IRB

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

**Human Research Protection Program
490 Illinois Street
Floor 6
San Francisco, CA 94158**

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

*City: **San Francisco** *State/Province: **CALIFORNIA** *Zip/Postal Code: **94158**

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

*Phone: **415 476-1814** *FAX: **415 353-4418** *E-Mail: **irb@ucsf.edu**

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

5

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):

642

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):

110

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:

373

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

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

H. IRB Chairperson

*First Name: **Alan** Middle Initial: *Last Name: **Venook**

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

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

Human Research Protection Program

490 Illinois Street

Floor 6

San Francisco, CA 94158

City: **San Francisco** State/Province: **CALIFORNIA** Zip/Postal Code: **94158**

Country (if outside the U.S.):

*Phone: **415 476-1814** FAX: *E-Mail: **alan.venook@ucsf.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
Venook, Alan	M	MD	S	Hematology/Onc	Y	Primary Member (Chair)
Brand, Norman	M	PhD, JD	N	Arbitration/ Dispute resolution	N	Primary Member (Community Member)
Robbins, Elizabeth	F	MD	S	Pediatric Hematology Oncology	Y	Primary Member
Miller, Warren	M	JD	N	Law and Finance	Y	Primary Member
Warren, Robert	M	MD	S	Surgery	Y	Primary Member
Okumura, Megumi	F	MD, MAS	S	Pediatrics	Y	Primary Member (Vice Chair)
Daud, Adil	M	MD	S	Hematology/Oncolo gy; Melanoma	Y	Primary Member (Vice Chair)
Kolodzie, Kerstin	F	MD, PhD, MAS	S	Anesthesiology	Y	Primary Member
Yefimova, Maria	F	RN, PhD	S	Nursing	Y	Primary Member
Ohliger, Michael	M	MD, PhD	S	Radiology	Y	Primary Member
O'Riordan, David	M	PhD	S	Palliative Medicine	Y	Primary Member
Kwon, Daniel H.	M	MD	S	Genitourinary medical oncology	Y	Primary Member

Alternative Members

Jones, Reese	M	MD	S	Psychiatry, Drug Dependence	Y	Alternate for all Scientists (S)
Wara, Diane W.	F	MD	S	Pediatrics, HIV/AIDS, Immunology	Y	Alternate for all Scientists (S)
Bersot, Thomas P.	M	MD, PhD	S	Cardiovascular Disease	Y	Alternate for all Scientists (S)
Reus, Victor	M	MD	S	Psychiatry	Y	Alternate for all Scientists (S)
Fung, Gordon L.	M	MD, MPH, PhD	S	Cardiology	Y	Alternate for all Scientists (S)
Tioupine, Liz	F	BS, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Chao, Karen	F	BS, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Katz, Patricia	F	PhD	S	Outcomes Research/Psychosoc ial Issues	Y	Alternate for all Scientists (S)
Bugatto, Annette	F	BA, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)

Mickalian, Joanne	F	MS, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Viele, Carol	F	RN, MS, CNS	S	Hematology/Oncology	Y	Alternate for all Scientists (S)
Tulsky, Jacqueline P.	F	MD	S	Internal Medicine, HIV	Y	Alternate for all Scientists (S)
Etter, Cheri	F	BS, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Nolan, Katherine	F	MPH, CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Phillips, Jessica	F	BA	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Simpkins, Karen	F	MLS	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Goldberger, Wendy	F	MS	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Wang, Zhen	F	MD	S	Radiology	Y	Alternate for all Scientists (S)
Denis, Randy	M	MSN, CIP	S	Nursing	Y	Alternate for all Scientists (S)
Din, Imad	M	BS	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Keenan, Jason	M	MS, CIP	S	Regulatory Science	Y	Alternate for all Scientists (S)
Lobo, Errol	M	MD, PhD	S	Anesthesia and Perioperative Care	Y	Alternate for all Scientists (S)
Mueller, Sabine	F	MD, PhD	S	Pediatrics	Y	Alternate for all Scientists (S)
Vargas, Iya	F	BS	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Hagan-Colyar, Taylar	F	BS, CIP, CHES	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Grosvenor, Jonathan	M	CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Cooperberg, Matthew	M	MD	S	Medicine-Urology	Y	Alternate for all Scientists (S)
Koger-Hunt, Janae	F	MA	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Henderson, Susanne	F	RN	S	Nursing	Y	Alternate for all Scientists (S)
Patel, Ami	F	MPH	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Coons, Erin	F	MCR, CIP, RAC	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Meyer, Kelsey	F	MA	N	HRPP Admin	Y	Alternate for non-scientist

						(NS)
Swearingen, William	M	JD	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Feaman, Sara	F	MS, CCRP	S	Applied Analytics	Y	Alternate for all Scientists (S)
Heredia, Alejandro	M	MA	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Teran, Angie	F	MA	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Hancer, Lana	F	MPH, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Velez, Mario	M	AA	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Hildebrandt, Isabel	F	PhD, CIP	S	AI	Y	Alternate for all Scientists (S)
Tabbutt, Sarah	F	MD, PhD	S	Pediatrics	Y	Alternate for all Scientists (S)
Donnelly, Sarah	F	MA, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Irwin, Beth	F	MA, LPC, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)

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: **IRB00012543**

(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 California San Francisco IRB #5

C. Location of the IRB

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

**Human Research Protection Program
490 Illinois Street
Floor 6
San Francisco, CA 94158**

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

*City: **San Francisco** *State/Province: **CALIFORNIA** *Zip/Postal Code: **94158**

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

*Phone: **415 476-1814** *FAX: **415 353-4418** *E-Mail: **irb@ucsf.edu**

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

5

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):

216

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):

22

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:

75

‡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: **Jennifer** Middle Initial: *Last Name: **Michlitsch**

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

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

Human Research Protection Program

490 Illinios Street

Floor 6

San Francisco, CA 94158

City: **SAN FRANCISCO** State/Province: **CALIFORNIA** Zip/Postal Code: **94158**

Country (if outside the U.S.):

*Phone: **415 476-1814** FAX: **415 353-4418** *E-Mail: **Jennifer.Michlitsch@ucsf.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
Michlitsch, Jennifer	F	MD	S	Pediatric Hem/Oncology	Y	Primary Member (Chair)
D'Harlingue, Arthur	M	MD	S	Neonatology	Y	Primary Member (Vice Chair)
Madden, Jacqueline	F	RN, PNP	S	Gastroenterology, Rare Diseases	Y	Primary Member
Wara, Diane	F	MD	S	Pediatrics	Y	Primary Member
Gordon, Karen	F	BS	N	Community Member	N	Primary Member (Community Member)
Leibovich, Sara	F	MD	S	Pediatric emergency medicine	Y	Primary Member
Chesser, Hannah	F	MD	S	Pediatric Endocrinology and Diabetes	Y	Primary Member
Johnston, Christine	F	MLS	N	Community Member and Patient Advocate	N	Primary Member (Community Member)
Nguyen, Tuan	M	PharmD	S	Inpatient Pharmacy	Y	Primary Member
Alternative Members						
Leong, Kimery	F	PharmD	S	Research Pharmacist	Y	Alternate for all Scientists (S)
Koger-Hunt, Janae	F	MA	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Keenan, Jason	M	MS, CIP	S	Regulatory Science	Y	Alternate for all Scientists (S)
Stinson, Joel	M	CIP	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Venook, Alan	M	MD	S	Hematology/Onc	Y	Alternate for all Scientists (S)
Henderson, Susanne	F	RN	S	Nursing	Y	Alternate for all Scientists (S)
Tabbutt, Sarah	F	MD, PhD	S	Pediatrics	Y	Alternate for all Scientists (S)
Denis, Randy	M	MSN, CIP	S	Nursing	Y	Alternate for all Scientists (S)
Patel, Ami	F	MPH	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Coons, Erin	F	MCR, CIP, RAC	N	HRPP Admin	Y	Alternate for non-scientist (NS)

Meyer, Kelsey	F	MA	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Swearingen, William	M	JD	N	HRPP Admin	Y	Alternate for non-scientist (NS)
Okumura, Megumi	F	MD, MAS	S	Pediatrics	Y	Alternate for all Scientists (S)
Feaman, Sara	F	MS, CCRP	S	Applied Analytics	Y	Alternate for all Scientists (S)
Heredia, Alejandro	M	MA	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Teran, Angie	F	MA	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Hancer, Lana	F	MPH, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Reus, Victor	M	MD	S	Psychiatry	Y	Alternate for all Scientists (S)
Lobo, Errol	M	MD	S	Anesthesia and Perioperative Care	Y	Alternate for all Scientists (S)
Viele, Carol	F	RN, MS, CNS	S	Hematology/Oncology	Y	Alternate for all Scientists (S)
Bersot, Thomas	M	MD	S	Cardiovascular disease	Y	Alternate for all Scientists (S)
Tulsky, Jacqueline P.	F	MD	S	Internal Medicine, HIV	Y	Alternate for all Scientists (S)
Leslie, Kieron	M	MD	S	Dermatology	Y	Alternate for all Scientists (S)
Jones, Reese	M	MD	S	Psychiatry, Drug Dependence	Y	Alternate for all Scientists (S)
Katz, Patricia	F	PhD	S	Outcomes research, psychosocial issues	Y	Alternate for all Scientists (S)
Venook, Alan	M	MD	S	Hematology/Onc	Y	Alternate for all Scientists (S)
Fung, Gordon L.	M	MD, MPH, PhD	S	Cardiology	Y	Alternate for all Scientists (S)
Velez, Mario	M	AA	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Chao, Karen	F	BS, PhD, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Tioupine, Liz	F	BS, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Mickalian, Joanne	F	MA, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Etter, Cheri	F	BS, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Nolan, Kathryn	F	MPH, CIP	N	HRPP Admin	Y	Alternate for non-scientists

							(NS)
Phillips, Jessica	F	BA	N	HRPP Admin	Y		Alternate for non-scientists (NS)
Simpkins, Karen	F	MLS	N	HRPP Admin	Y		Alternate for non-scientists (NS)
Goldberger, Wendy	F	MS	N	HRPP Admin	Y		Alternate for non-scientists (NS)
Din, Imad	M	BS	N	HRPP Admin	Y		Alternate for non-scientists (NS)
Grosvenor, Jonathan	M	CIP	N	HRPP Admin	Y		Alternate for non-scientists (NS)
Hagan-Colyar, Taylar	F	BS, CIP, CHES	N	HRPP Admin	Y		Alternate for non-scientists (NS)
Vargas, Iya	F	BS	N	HRPP Admin	Y		Alternate for non-scientists (NS)
Bugatto, Annette	F	BA, CIP	N	HRPP Admin	Y		Alternate for non-scientists (NS)
Hildebrandt, Isabel	F	PhD, CIP	S	AI	Y		Alternate for all Scientists (S)
Daud, Adil	M	MD	S	Hematology/Oncology; Melanoma	Y		Alternate for all Scientists (S)
Donnelly, Sarah	F	MA, CIP	N	HRPP Admin	Y		Alternate for non-scientists (NS)
Irwin, Beth	F	MA, LPC, CIP	N	HRPP Admin	Y		Alternate for non-scientists (NS)

NOTES:

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

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

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

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

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

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

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

Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: **IRB00014103**

(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):

University of California, San Francisco IRB #6

C. Location of the IRB

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

**Human Research Protection Program
490 Illinois Street
Floor 6
San Francisco, CA 94158**

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

*City: **San Francisco** *State/Province: **CALIFORNIA** *Zip/Postal Code: **94158**

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

*Phone: **415 476-1814** *FAX: **415 353-4418** *E-Mail: **irb@ucsf.edu**

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

5

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):

0

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

0

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

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

0

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

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

H. IRB Chairperson

*First Name: **Gordon L.** Middle Initial: *Last Name: **Fung**

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

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

Human Research Protection Program

490 Illinois Street

Floor 6

San Francisco, CA 94158

City: **San Francisco** State/Province: **CALIFORNIA** Zip/Postal Code: **94158**

Country (if outside the U.S.):

*Phone: **415 476-1814** FAX: *E-Mail: **gordon.fung@ucsf.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
Fung, Gordon L.	M	MD, MPH, PhD	S	Cardiology	Y	Primary Member (Chair)
Tabbutt, Sarah	F	MD, PhD	S	Pediatrics	Y	Primary Member (Vice Chair)
Brand, Norman	M	PhD, JD	N	Arbitration/Dispute Resolution	N	Primary Member (Community Member)
Salahuddin, Ayesha	F	MD	S	Cardiology	Y	Primary Member
Schwartz, Janice B	F	MD	S	Geriatric cardiovascular pharmacology	Y	Primary Member
Yang, Joseph	M	MD	S	Cardiology/Interven tional Cardiology	Y	Primary Member
Fischer, Robin	F	DNP, FNP-C	S	Cardiovascular, Heart Failure	Y	Primary Member

Alternative Members

Bersot, Thomas	M	MD, PhD	S	Cardiovascular Disease	Y	Alternate for all Scientists (S)
D'Harlingue, Arthur	M	MD	S	Neonatology	Y	Alternate for all Scientists (S)
Jones, Reese	M	MD	S	Psychiatry, Drug Dependence	Y	Alternate for all Scientists (S)
Katz, Patricia	F	PhD	S	Outcomes research, psychosocial issues	Y	Alternate for all Scientists (S)
Leslie, Kieron	M	MD	S	Dermatology	Y	Alternate for all Scientists (S)
Lobo, Errol	M	MD	S	Anesthesia and Perioperative Care	Y	Alternate for all Scientists (S)
Michlitsch, Jennifer	F	MD	S	Pediatric Hem/Oncology	Y	Alternate for all Scientists (S)
Okumura, Megumi	F	MD, MAS	S	Pediatrics	Y	Alternate for all Scientists (S)
Reus, Victor	M	MD	S	Psychiatry	Y	Alternate for all Scientists (S)
Tulsky, Jacqueline	F	MD	S	Internal Medicine, HIV	Y	Alternate for all Scientists (S)
Venook, Alan	M	MD	S	Hematology/Oncolo gy	Y	Alternate for all Scientists (S)
Viele, Carol	F	RN, MS, CNS	S	Hematology/Oncolo gy	Y	Alternate for all Scientists (S)

Wara, Diane	F	MD	S	Pediatrics	Y	Alternate for all Scientists (S)
Keenan, Jason	M	MS, CIP	S	Regulatory Science	Y	Alternate for all Scientists (S)
Bugatto, Annette	F	BA, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Chao, Karen	F	BS, PhD, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Coons, Erin	F	MCR, CIP, RAC	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Denis, Randy	M	MSN, CIP	S	Nursing	Y	Alternate for all Scientists (S)
Din, Imad	M	BS	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Etter, Cheri	F	BS, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Feaman, Sara	F	MS, CCRP	S	Applied Analytics	Y	Alternate for all Scientists (S)
Goldberger, Wendy	F	MS	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Grosvenor, Jonathan	M	CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Hagan-Colyar, Taylar	F	BS, CIP, CHES	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Hancer, Lana	F	MPH, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Henderson, Susanne	F	RN	S	Nursing	Y	Alternate for all Scientists (S)
Heredia, Alejandro	M	MA	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Hildebrandt, Isabel	F	PhD, CIP	S	AI	Y	Alternate for all Scientists (S)
Koger-Hunt, Janae	F	MA	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Meyer, Kelsey	F	MA	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Mickalian, Joanne	F	MA, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Nolan, Kathryn	F	MPH, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Patel, Ami	F	MPH	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Phillips, Jessica	F	BA	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Simpkins, Karen	F	MLS	N	HRPP Admin	Y	Alternate for non-scientists

						(NS)
Stinson, Joel	M	CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Swearingen, William	M	JD	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Teran, Angie	F	MA	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Tioupine, Liz	F	BS, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Vargas, Iya	F	BS	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Velez, Mario	M	AA	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Daud, Adil	M	MD	S	Hematology/Oncology; Melanoma	Y	Alternate for all Scientists (S)
Donnelly, Sarah	F	MA, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)
Irwin, Beth	F	MA, LPC, CIP	N	HRPP Admin	Y	Alternate for non-scientists (NS)

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.

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.*