

Submission#: **34922**
IORG#: **IORG0000147**
Institution: **U of Louisville**

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

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

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

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

This form is to be used for the following purposes:

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

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

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

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

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

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

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

2. *What is your institution or organization (IORG) number? IORG0000147

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.

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: **IRB00000251**

(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 Louisville IRB #1 - Biomedical

C. Location of the IRB

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

**Human Subjects Protection Program Office
MedCenter One
501 E. Broadway, Suite 200**

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

*City: **Louisville** *State/Province: **KENTUCKY** *Zip/Postal Code: **40202-1798**

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

*Phone: **502 852-5188** *FAX: **502 852-2164** *E-Mail: **hsppofc@louisville.edu**

D. ♦Approximate number of full time equivalent positions devoted to the IRB's administrative activities: **12**

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): **1122**

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): **203**

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:

247

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

- | | |
|---|--|
| <input checked="" type="checkbox"/> human drugs | <input checked="" 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: **Laura** Middle Initial: **D** *Last Name: **Clark**

Earned Degree(s): **MD** Title or Position: **IRB Chairperson/Assoc Professor, Anesthesiology**

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

Human Subjects Protection Program

MedCenter One - Suite 200

501 E. Broadway

City: **Louisville** State/Province: **KENTUCKY** Zip/Postal Code: **40202-1798**

Country (if outside the U.S.):

*Phone: **502 852-5188** FAX: **502 852-2164** *E-Mail: **llclar02@louisville.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
Clark, Laura	F	MD	S	Anesthesiology	Y	UofL, Womens Advocate
Barrer, Sharon	F	ADAS, Nursing	S	Family & Geriatric Medicine	Y	Research Coordinator, SOM, Advocate for Vulnerable Populations-Elderly
Carreon, Leah Y	F	M.D., M.Sc.	S	Surgery-Orthopedic Surgery	N	Research Director, Leatherman Spine Center, Norton Healthcare
Coram, Rita	F	M.D.	S	Medicine- Cardiology	Y	SOM, Asst Prof, UofL
Dryden, Gerald W	M	M.D.	S	Medicine- Gastroenterology/H epatology	Y	Assoc Professor, UofL
Flynn, Michael B.	M	M.D.	S	Surgery-Surgical Oncology	Y	SOM, Professor, UofL
Goldman, Julie L	F	M.D.	S	Surgery-Pediatric Otolaryngology	Y	Vice Chair, Clin Assoc Professor, UofL, Advocate for Children
Groff, Diller B.	M	M.D.	S	Surgery-Pediatric Surgery	Y	Vice Chair, SOM, Clin Professor, UofL, Children's Advocate
Quesada, Peter M	M	Ph.D.	N	Engineering	Y	Chair, SBE IRB, Assoc Prof, UofL
Martinez, Serge A	M	M.D., J.D.	S	Surgery- Otolaryngology, Bioethics,	N	Vice Chair, Community minority member, Adv for vulnerable populations
Stenger, Robert L.	M	J.D.	N	Law	N	Community Member, Women's Advocate
Sullivan, Janice E.	F	M.D.	S	Pediatrics-Critical Care Medicine	Y	Professor, UofL, Children's Advocate
Whalen, Cathy A.	F	Pharm.D	S	Health Policy and Research	Y	Director, Health policy, Research Pharmacy, UofL Hospital, Adv for vulnerable po
Moll, John	M	B.S.	N	Certified Public Accountant	N	Community member, Advocate for Vulnerable Populations
Woolridge, Linda	F	MBA	N	MBA, Community Member	N	Community Member, Minority member

Alternative Members

Martinez, Serge A.	M	M.D., J.D.	S	Surgery-ENT	N	Vice Chair, Community Member: Alt for 1, 3, 4, 5 8, 12
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Casanova, Manuel F.	M	M.D.	S	SS/PS, Psychiatry/Beh Sci.	Y	SOM, Prof, UofL, Minori Adv for Cogn Imp, Alt: 1 6, 7, 8, 12
Vaughn, Vida	F	BGS, MLIS	S	Library Science	Y	Alt for: 2, 10, 13
DeFilippis, Andrew P.	M	M.D.	S	Medicine-Cardiovascular Services	Y	SOM, Assistant Professor Alt. for 1,3,4, 5, 6, 7, 8, 1
Trachtenberg, Laura S	F	B.S., M.A.	S	Surgery-Research	Y	Alt for: 2, 10, 13
Beatty, Karen S.	F	ADAS, Nursing	S	Nursing	Y	Res. Coord, Med-GI, Alt 10, 13
Abou-Chebl, Alex	M	M.D.	S	Neurology/Medicine	Y	SOM, Assoc Prof, UofL, 1,3,4, 5, 6, 7, 8, 12
Radmacher, Paula	F	Ph.D.	S	Pediatrics-Neonatology	Y	Research Mgr, UofL, Chi advocate, Alt for: 2, 10, 1
Coldwell, Douglas M.	M	M.D.	S	Medicine-Radiology	Y	Asst Professor, UofL, Alt 1,3,4, 5, 6, 7, 8, 12
Binkley, Catherine J.	F	DDS, MSPH, PhD	S	Dentistry	Y	Assoc. Prof, Dentistry, Al 2, 10, 13
Kaufman, Christina	F	Ph.D.	S	Transplantation specialist	N	Alternate for 2, 10, 13
Redman, Rebecca	F	M.D.	S	Medical Oncology	Y	SOM, Asst Prof, Alt for: 5, 6, 7, 8, 12
Deuth, Doris W.	F	B.A., M.A.	N	Criminal Science	N	Community Mbr, Prisone Alt for: 9, 11, 14
Hanson, Stephen S.	M	Ph.D.	N	Bioethics/Family Medicine	Y	SOM, UofL, Alt for: 9, 11
Berkenbosch, John	M	M.D.	S	Pediatrics	Y	SOM-Prof, Childrens Adv Alt for: 1,3,4,5, 6, 7, 8, 12
Taylor, Cicek	F	Ph.D.	S	Obstetrics, Gynecology and Womens Health	Y	SOM, Assoc Prof., Alt fo 13

NOTES:

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

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

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

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

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

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

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

[X] Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: **IRB00000252**

(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 Louisville IRB #2 - Behavioral

C. Location of the IRB

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

**Human Subjects Protection Program Office
MedCenter One
501 E. Broadway, Suite 200**

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

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D. ♦Approximate number of full time equivalent positions devoted to the IRB's administrative activities: **12**

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): **343**

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): **43**

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):

human drugs	food additives
medical devices	color additives
biological	<input checked="" type="checkbox"/> other
	Specify: None

H. IRB Chairperson

*First Name: **Peter** Middle Initial: *Last Name: **Quesada**

Earned Degree(s): **Ph.D.** Title or Position: **IRB Chair**

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

MedCenter One

501 E. Broadway- Suite 200

City: **Louisville** State/Province: **KENTUCKY** Zip/Postal Code: **40202-1798**

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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
Quesada, Peter	M	Ph.D.	S	School of Engineering	Y	IRB Chair, Professor, UofL, Advocate for cognitively impaired
Andris, Melissa Evans	F	Ph.D.	S	Sociology/Education & Human Development	Y	Assoc Dean, CEHD, UofL,
Hall, Timothy	M	J.D.	N	Law	Y	Brandeis School of Law, Professor, UofL
Hanson, Stephen S.	M	Ph.D.	N	Family & Geriatric Medicine/Philosophy	Y	Research Fellow-Inst for Bioethics, Med & Law, Adv for Vuln Pops
Cumberland, Denise	F	Ph.D.	S	Education-Human Development	Y	Asst. Professor, UofL
Munoz, Marco	M	Ph.D.	S	Education & Human Development	N	Sr Analyst, Jefferson Co. Public Schools, Minority Member, Children's Adv
Ridner, S. Lee	M	Ph.D.	S	Nursing	Y	Associate Professor, UofL, Advocate for vulnerable populations
Camargo, Crystal Collins	F	Ph.D.	S	Social Work	Y	Assistant Prof., School of Social Work, Advocate for Children
Schapmire, Tara J.	F	M.S.S.W., Ph.D.	S	Medical Social Work	Y	School of Social Work
Death, Doris W	F	B.A., M.A.	N	Community Member	N	Retired Warden, Prisoner Advocate
Newton, Tamara L.	F	Ph.D.	S	Psychological & Brain Sciences	Y	Assoc Prof, UofL, Arts & Sciences, Adv for Women
Golder, Seana	F	Ph.D.	S	Social Work	Y	Associate Prof., School of Social Work, Advocate for Women & Children
Alternative Members						
Smigielski, Elizabeth M.	F	M.S.L.S.	N	Librarian	Y	Assoc Prof, UofL, Alt. fo
Berger, Jill T	F	RN, MBA	S	Nursing	N	Director, Patient Care Operations, Norton Health Alt for: 9, 11
Carpenter, Bradley W	M	Ph.D.	S	Education-Educational Administration	Y	Education, Asst Prof, Alt 2, 3, 4, 6, 10, 12
Lau, Timothy S.	M	B.A., M.S.	S	Ph.D. Student, Educational Psychology	Y	Alt for 1, 2, 3, 4, 6, 10, 12

NOTES:

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Public burden for this collection of information is estimated to average one hour for an initial IRB registration, and thirty minutes for updating or renewing the registration of a previously registered IRB. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: OS Reports Clearance Officer, Room 503, 200 Independence Avenue, SW., Washington, DC 20201. *Do not return the completed form to this address.*