

IORG #: **IORG0000250**
Institution: **U of Kentucky**
Expires: **02/28/2015**

OMB No. 0990-0279
Approved for use through June 30, 2012

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? IORG0000250**

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 Kentucky**

*Mailing Address: **315 Kinkead Hall**
University of Kentucky

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

*City: **Lexington** *State/Province: **KENTUCKY** *Zip/Postal Code: **40506-0057**

*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: **James** Middle Initial: **W** *Last Name: **Tracy**

Earned Degree(s): **Ph.D.** Title or Position: **Vice President for Research**

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

University of Kentucky
311 Main Building

*City: **Lexington** *State/Province: **KENTUCKY** *Zip/Postal Code: **40506-0033**

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

*Phone: **859 257-5294** *FAX: **859 323-2800** *E-Mail: **jtracy@uky.edu**

5. Contact Person Providing this Registration Information

*First Name: **Judi** Middle Initial: **L** *Last Name: **Kuhl**

Earned Degree(s): **BS, CIP** Title or Position: **Quality Improvement Program
Coordinator, Office of Research
Integrity**

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

University of Kentucky

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

408 Kinkead Hall
University of Kentucky

*City: **Lexington** *State/Province: **KENTUCKY** *Zip/Postal Code: **40506-0057**

*Country (if outside the

*Phone: **859 257-9764** *FAX: **859 323-9882** *E-Mail: **judi.kuhl@uky.edu**

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: **IRB00000423**

(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 Kentucky IRB #1 - Med Monday

C. Location of the IRB

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

**315 Kinkead Hall
University of Kentucky**

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

*City: **Lexington** *State/Province: **KENTUCKY** *Zip/Postal Code: **40506-0057**

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

*Phone: **859 257-9764** *FAX: **859 323-9882** *E-Mail: **judi.kuhl@uky.edu**

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

4

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):

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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):

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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:

80

‡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: **Patrizio** Middle Initial: *Last Name: **Capasso**

Earned Degree(s): **MD, DSc** Title or Position: **Professor**

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

University of Kentucky

c/o Office of Research Integrity

City: **Lexington** State/Province: **KENTUCKY** Zip/Postal Code: **40506-0057**

Country (if outside the U.S.):

*Phone: **859 323-8390** FAX: *E-Mail: **pnca222@email.uky.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
Capasso, Patrizio	M	MD, DSc	S	Vascular & Interventional Radiology	Y	Physician Scientist, exp 8/31/14
Cibull, Michael L.	M	MD	S	Pathology	Y	Physician Scientist, Vice Chair, exp 8/31/12
Wolf, Lyle	M	BE	N	Engineering (Retired)	N	Nonscientist, Community Member, exp 8/31/14
Blumenschein, Karen	F	PharmD	S	Pharmacology, Behavioral Science	Y	Other Scientist, Social Scientist, Vice Chair, exp 8/31/14
Noonan, Jacqueline	F	MD	S	Pediatrics	Y	Physician Scientist, Childrens Advocate, exp 8/31/13
Jenkins, Lee	M	BA	N	Business	N	Nonscientist, Community Member, exp 8/31/14
Frazier, Susan	F	PhD, RN	S	Nursing Instruction	Y	Other Scientist, exp 8/31/14
Thompson, John	M	MD	S	Internal Medicine	Y	Physician Scientist, exp 8/31/2013
Lile, Joshua	M	PhD	S	Behavioral Science	Y	Social Scientist, exp 8/31/14
Craven, Rolf	M	PhD	S	Molecular & Biomed Pharmacology	Y	Other Scientist, exp 8/31/14

Alternative Members

Logan, T. K.	F	PhD	S	Applied Psychology	Y	Social Scientist, Priso Rep, Parental Perspec exp 8/31/13
Taylor, Kathy	F	MS	N	Corrections Administration	N	Nonscientist, Commu Member, Prisoner Re 8/31/14
Dawson, Dolph	M	DMD, MS	S	Oral Health Practice	Y	Other Scientist, exp 8/31/14
Casey, Baretta	F	MD, FAFFP	S	Family Medicine	Y	Physician & Social Scientist, Appalachian/Rural Medicine Rep, exp 8/
Kelly, Thomas H.	M	PhD	S	Behavioral Science	Y	Social Scientist, exp 8/31/14
StatonTindall, Michelle	F	PhD	S	Social Work	Y	Social Scientist, Priso Rep, exp 8/31/13
Thompson, LaDonna	F	BA	N	Psychology and Corrections	N	Other Scientist, Priso Rep, exp 8/31/13
Kimbrell, William	M	BS	S	Biology	N	Other Scientist, Community Member

							8/31/12, MED only
Shapiro, Robert	M	PhD	S	Exercise Physiology	Y		Other Scientist, exp 8/31/14
Berry, David	M	PhD	S	Psychology	Y		Social Scientist, Vice-Chair, exp 8/31/14, NMED Mtg Alt
Hansen, Gary	M	PhD	S	Sociology	Y		Social Scientist, Child Advocate, exp 8/31/14, NMED Mtg Alt
Crystal, Ralph	M	PhD	S	Educational Psychology	Y		Social Scientist, Child Advocate, exp 8/31/14, NMED Mtg Alt
Giancola, Peter	M	PhD	S	Clinical Psychology	Y		Social Scientist, exp 8/31/13, NMED Mtg Alt
Lyon, Sarah	F	PhD	S	Anthropology	Y		Social Scientist, exp 8/31/11, NMED Mtg Alt
Clark, James	M	PhD	S	Social Work	Y		Social Scientist, Prison Rep, exp 8/31/14, NMED Mtg Alt
Beighle, Aaron	M	PhD	S	Physical Education/Kinesiology	Y		Other Scientist, exp 8/31/14
McCormick, Malkanthie	F	MBBS	S	Infectious Disease	Y		Physician Scientist, Parental Perspective, 8/31/12
Still, Alicia	F	JD	N	Legal	N		Nonscientist, Community Member, exp 8/31/12, NMED Mtg Alt
Olszewsky, Steven	M	PhD, JD, MBA	S	Legal	N		Community Member 8/31/12, MED & NMED
Meyer, Janice	F	BA	N	Education	N		Nonscientist, Community Member, exp 8/31/12, MED & NMED
Chambers, Mara	F	MD	S	Oncology, Internal Medicine	Y		Physician Scientist, exp 8/31/14, NCI CIRB /
Howard, Patricia	F	PhD, RN, CEN, CPEN,	S	Nursing	Y		Other Scientist, XP M & NMED Children's Advocate, Parental Perspective, exp 8/31/14
Grisham-Brown, Jennifer	F	EdD	S	Early Childhood Development	Y		Social Scientist, Child Advocate, exp 8/31/14, NMED Mtg Alt
Miller-Spillman, Kimberly	F	PhD	S	Environmental Sciences	Y		Other Scientist, Survey Research, exp 8/31/14, NMED Mtg Alt
Chishti, Aftab	M	MD, FAAP, CSST	S	Pediatrics	Y		Physician Scientist, Children's Advocate, 8/31/14

Jicha, Gregory	M	MD, PhD	S	Neurology	Y	Physician Scientist, Impaired Consent Capacity, exp 8/31/14, MED & NONMED
Basuray, Rita	F	PhD	S	Reproductive Health, Biospecimen Storage	Y	Other Scientist, exp 8/31/14, MED
Bhatt, Ramesh	M	PhD	S	Psychology	Y	Social Scientist, exp 8/31/14, NMED Mtg
Ryan, Stephen	M	MD	S	Neurology	Y	Physician Scientist, Adult NCI-CIRB, exp 8/31/14
Fillmore, Mark	M	PhD	S	Psychology	Y	Social Scientist, exp 8/31/13, SURE, NMED Mtg Alt
Walker, Robert	M	MSW, LCSW, MDiv	S	Social Work	Y	Social Scientist, Prison Rep, Impaired Consent Capacity, exp 8/31/12
Saha, Sibuj	M	MD, MBA	S	Cardiothoracic Surgery	Y	Physician Scientist, NCI-XP Reviewer, exp 8/31/14
Kurzynske, Janet	F	PhD, RD	S	Nutrition and Food Science	Y	Social Scientist, NCI-Mtg Alt, XP & XX Reviewer, exp 8/31/14
Clasey, Jody	F	PhD, FACSM	S	Exercise Physiology/Bone Densitometry	Y	Other Scientist, Child Advocate, MED, exp 8/31/14

NOTES:

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

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

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

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

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

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

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

Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: **IRB00000424**

(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 Kentucky IRB #2 - Med Tuesday

C. Location of the IRB

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

**315 Kinkead Hall
University of Kentucky**

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

*City: **Lexington** *State/Province: **KENTUCKY** *Zip/Postal Code: **40506-0057**

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

*Phone: **859 257-9764** *FAX: **859 323-9882** *E-Mail: **judi.kuhl@uky.edu**

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

4

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):

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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):

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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:

80

‡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: **Larry** Middle Initial: *Last Name: **Cunningham, Jr.**

Earned Degree(s): **MD, DDS** Title or Position: **Associate Professor**

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

University of Kentucky

c/o Office of Research Integrity

City: **Lexington** State/Province: **KENTUCKY** Zip/Postal Code: **40506-0057**

Country (if outside the U.S.):

*Phone: **859 323-6101** FAX: *E-Mail: **llcunn2@email.uky.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
Cunningham, Jr., Larry	M	MD, DDS	S	Oral & Maxillofacial Surgery	Y	Physician Scientist, exp 8/31/14
Hirschowitz, Edward	M	MD	S	Pulmonary Oncology	Y	Physician Scientist, Vice Chair, exp 8/31/14
White, Carol	F	MPH	S	Epidemiology	Y	Other Scientist, exp 08/31/13
Whayne, Thomas	M	MD	S	Cardiology	Y	Physician Scientist, exp 08/31/12
Skaff, Karen	F	PhD	S	Higher Education	Y	Social Scientist, Parental Perspective, exp 8/31/12
Spiker, James	M	MS	N	Colonel US Army (Retired)	N	Nonscientist, Community Member, exp 08/31/14
Shook, Lori	F	MD	S	Pediatrics	Y	Physician Scientist, Vice Chair, Children Advocate, Pregnant Women, exp 8/31/14
Wilson, George	M	N/A	N	Business	N	Nonscientist, Community Member, exp 08/31/14
High, Walter	M	PhD	S	Physical Medicine & Rehabilitation	Y	Other Scientist, Impaired Consent Capacity, exp 8/31/13
Rinehart, John	M	MD	S	Oncology, Blood & Marrow Transplantation	Y	Physician Scientist, NCI CIRB Adults, exp 8/31/13
Humphries, Roger	M	MD	S	Emergency Medicine	Y	Physician Scientist; exp 8/31/2013

Alternative Members

NOTES:

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

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

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

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

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: **IRB00000977**

(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 Kentucky IRB #3 - Med Thursday

C. Location of the IRB

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

**315 Kinkead Hall
University of Kentucky**

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

*City: **Lexington** *State/Province: **KENTUCKY** *Zip/Postal Code: **40506-0057**

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

*Phone: **859 257-9764** *FAX: **859 323-9882** *E-Mail: **judi.kuhl@uky.edu**

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

4

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):

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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

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the IRB conducted an initial review or 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:

80

‡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: **Terry** Middle Initial: *Last Name: **Malone**

Earned Degree(s): **Ed.D.** Title or Position: **Professor**

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

University of Kentucky

C/o Office of Research Integrity

City: **Lexington** State/Province: **KENTUCKY** Zip/Postal Code: **40506-0057**

Country (if outside the U.S.):

*Phone: **859 323-1100** FAX: *E-Mail: **trmal01@email.uky.edu**
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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
Malone, Terry	M	Ed.D.	S	PT Assessment	Y	Other Scientist, exp 8/31/14
Hahn, Ellen J.	F	RN, PHD	S	Drug Prevention	Y	Social Scientist, Parental Perspective, exp 8/31/14
Holleman, Donald	M	MD	S	Internal Medicine	Y	Physician Scientist, Vice Chair, exp 8/31/14
Rice, Linda	F	RN	S	Nursing	Y	Other Scientist, Social Scientist, Parental Perspective, exp 8/31/13
Thornton, Alice	F	MD	S	Infectious Diseases	Y	Physician Scientist, Parental Perspective, exp 8/31/13
Damm, Douglas	M	DDS	S	Dental Pathology	Y	Other Scientist, exp 8/31/13
Harper, Lee	M	N/A	N	Business	N	Nonscientist, Community Member, exp 8/31/14
Tran, Tuyen	M	MD	S	Emergency Medicine	N	Physician Scientist, exp 8/31/13
Davis, George	M	PharmD, BCPS	S	Pharmacy	Y	Other Scientist, exp. 8/31/13
Venkatesh, Ramakrishna	M	MD	S	Urology	Y	Physician Scientist, exp 8/31/14

Alternative Members

NOTES:

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

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

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

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

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

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: **IRB00005975**

(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 Kentucky IRB #6 - Med Wednesday

C. Location of the IRB

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

**315 Kinkead Hall
University of Kentucky**

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

*City: **Lexington** *State/Province: **KENTUCKY** *Zip/Postal Code: **40506-0057**

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

*Phone: **859 257-9764** *FAX: **859 323-9882** *E-Mail: **judi.kuhl@uky.edu**

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

4

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):

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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

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the IRB conducted an initial review or 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:

80

‡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: **Terry** Middle Initial: *Last Name: **Malone**

Earned Degree(s): **Ed.D.** Title or Position: **Professor**

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

University of Kentucky

c/o Office of Research Integrity

City: **Lexington** State/Province: **KENTUCKY** Zip/Postal Code: **40506-0057**

Country (if outside the U.S.):

*Phone: **859 323-1100** FAX: *E-Mail: **trmal01@email.uky.edu**
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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
Malone, Terry	M	Ed.D.	S	PT Assessment	Y	Other Scientist, exp 8/31/14
Nelson, Bill	M	BS	N	Mathmatics	N	Nonscientist, Community Member, exp 8/31/14
Rush, Craig	M	PhD	S	Behavioral Science	Y	Social Scientist, Vice Chair, exp 08/31/13
McClung, Jeffrey	M	PhD	S	Exercise Physiology/Cardiac Rehab	Y	Other Scientist, exp 08/31/13
Perrine, William	M	BS	N	Chemical Engineer (Retired)	N	Nonscientist, Community Member, exp 8/31/14
Yepes, Juan	M	DDS, MD, MPH	S	Oral Health Practice	Y	Physician Scientist, Other Scientist, Vice Chair, exp 08/31/13
Fleischman, Roger	M	MD	S	Hematology/Oncolo gy	Y	Physician Scientist, exp 8/31/13
Duke, Mary	F	MD	S	Geriatrics, Pediatrics, Pathology	Y	Physician Scientist, Impaired Consent Cap., Children Adv., exp 8/31/14
Yannelli, John	M	PhD	S	Immunotherapy	Y	Other Scientist, exp 8/31/14
Carrico, Jeffery	M	PharmD	S	PharmD	Y	Other Scientist; exp 8/31/13
Cheung, Robyn	F	PhD, MSN	S	Nursing	Y	Other Scientist, Systems Improvement Facilitator, exp 8/31/14

Alternative Members

NOTES:

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

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

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

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

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