

Submission#: 20427
IORG#: IORG0000250
Institution: U of Kentucky & Dept VAMC-Facility 596

OMB No. 0990-0279
Approved for use 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 used by institutions or organizations operating IRBs that review:

- 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/asearch.asp#ASUR> 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 & Dept VAMC-Facility 596

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: **IORG0000250**

(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/asearch.asp#ASUR> 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 **20791**

*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):

322 Bosomworth Health Science Research Building

*City: **Lexington** *State/Province **KY** *Zip/Postal Code: **40536-0305**

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

*Phone: **859 257-8295** *FAX: **859 257-9700** *E-Mail: **aliten@email.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): **297**

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): **82**

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 products | other |
- Specify:

H. IRB Chairperson

*First Name: **Thomas** Middle Initial: *Last Name: **Foster**
Earned Degree(s): **Pharm.D.** Title or Position: **Professor, Executive Chair**

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

University of Kentucky
c/o Office of Research Integrity

*City: **Lexington** *State/Province **KY** *Zip/Postal Code: **40506-0057**
University of Kentucky
*Country (if outside the U.S.):

*Phone: **859 323-5329** *FAX: **859 323-1921** *E-Mail: **foster@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) or Non-scientist (N)	Primary Scientific or Non-Scientific Specialty	Affiliation with Institution(s) Y/N	Comments
Foster, Thomas	M	Pharm.D	Y	Pharmacology	Y	Other Scientist, exp 08/31/12
Cibull, Michael L.	M	MD	Y	Pathology	Y	Physician Scientist, exp 8/31/12
Wolf, Lyle	M	BE	N	Engineering (Retired)	N	Nonscientist, Community Member, exp 08/31/11
Dawson, Dolph	M	DMD, MS	Y	Oral Health Practice	Y	Other Scientist, Vice-Chair, exp 08/31/10
Blumenschein, Karen	F	PharmD	Y	Pharmacology, Behavioral Science	Y	Other Scientist, Social Scientist, Vice Chair, exp 08/31/11
Day, James	M	MD	Y	Internal Medicine/Pathology	Y	Physician Scientist, VA Rep, exp 08/31/10
Noonan, Jacqueline	F	MD	Y	Pediatrics	Y	Physician Scientist, Childrens Advocate, exp 08/31/10
Ryan, Stephen	M	MD	Y	Neurology/Psychiatry	Y	Physician Scientist, VA Representative, Decisionally Impaired, exp. 08/31/10
Roark-Trumble, Kimberley	F	MBA	N	Business	Y	Nonscientist, exp 08/31/11
Lineberry, Michelle	F	EdD	Y	Health Promotion Education	Y	Other Scientist, exp 08/31/12
Schwarze, Steven	M	PhD	Y	Cellular Biochemistry	Y	Other Scientist, exp 08/31/12
Capasso, Patrizio	M	MD	Y	Vascular & Interventional Radiology	Y	Physician Scientist, exp 08/31/12

Alternative Members

Hall, Debra		F	MSN	Nursing	Y	Other Scientist, exp 08/31/10
Seabold, Bill		M	BA	Corrections	N	Nonscientist, Prisoner Rep, exp 08/31/10
Jenkins, Lee		M	BA	Business	N	Nonscientist, Community Member, exp 08/31/11, MED & NMED
Lynch, Robert		M	DVM	Veterinary Medicine	N	Other Scientist, Community Member, exp 08/31/11, MED only
Taylor, Kathy		F	MS	Corrections Administration	N	Nonscientist, Community Member, Prisoner Rep, exp 08/31/11
Casey, Baretta		F	MD, FAFFP	Family Medicine	Y	Physician & Social Scientist, Appalachian/Rural Medical Center Rep, exp 08/31/10
Kelly, Thomas H.		M	PhD	Behavioral Science	Y	Social Scientist, exp 08/31/11
Kirsh, Ken		M	PhD	Hematology/Oncology	Y	Other Scientist, exp 08/31/10
Staton-Tindall, Michelle		F	PhD	Social Work	Y	Social Scientist, Prisoner Rep, exp 08/31/10
Logan, T. K.		F	PhD	Applied Psychology	Y	Social Scientist, Prisoner Rep, exp 08/31/10
Koch, Alvaro		M	MD	Transplant Surgery, Gastroenterology	Y	Physician Scientist, exp 08/31/11

Haas, Scott	M	MD	Psychiatry	N	Physician Scientist, Prisoner Rep, exp 08/31/10
Rees, John	M	MS	Criminology, Correctional Administration	N	Other Scientist, Prisoner Rep, exp 08/31/10
Kimbrell, William	M	BS	Biology	N	Other Scientist, Community Member, exp 08/31/12, MED only
Shapiro, Robert	M	PhD	Exercise Physiology	Y	Other Scientist, exp 08/31/11
Berry, David	M	PhD	Psychology	Y	Social Scientist, Vice-Chair, exp 08/31/12, NMED Mtg Alt
Janoski, Tom	M	PhD	Sociology	Y	Social Scientist, exp 08/31/11
Still, Alicia	F	JD	Legal	N	Nonscientist, Community Member, exp 08/31/12, NMED Mtg Alt
Thompson, LaDonna	F	BA	Psychology and Corrections	N	Social Scientist, Prisoner Rep, exp 08/31/10
Hansen, Gary	M	PhD	Sociology	Y	Social Scientist, Children Advocate, exp 08/31/10, NMED Mtg Alt
Crystal, Ralph	M	PhD	Educational Psychology	Y	Social Scientist, Childrens Advocate, Vice Chair, exp 08/31/12
Giancola, Peter	M	PhD	Clinical Psychology	Y	Social Scientist, exp 08/31/10, NMED Mtg Alt
Levstik, Linda	F	PhD	Social Studies/Humanities	Y	Social Scientist, exp 08/31/11, NMED Mtg Alt
Lyon, Sarah	F	PhD	Anthropology	Y	Social Scientist, exp 08/31/11, NMED Mtg Alt
Clark, James	M	PhD	Social Work	Y	Social Scientist, Prisoner Rep, exp 08/31/11, NMED Mtg Alt
Van Willigen, John	M	PhD	Anthropology	Y	Social Scientist, exp 08/31/11
Beighle, Aaron	M	PhD	Physical Education/Kinesiology	Y	Other Scientist, exp 08/31/11
McCormick, Malkanthie	F	MBBS	Infectious Disease	Y	Physician Scientist, exp 08/31/12
Million, George	M	MA	Counseling Psychology	N	Social Scientist, Prisoner Rep, exp 08/31/10
Sullivan, Don	M	AB	Political Science	N	Nonscientist, Community Member, exp 08/31/10, Med & NMED

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: **IORG0000250**

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No, this is a new IRB registration.

B. Provide the IRB name, if any, used by the institution or organization (e.g., State University Behavioral IRB, University Healthcare Biomedical IRB, or XYZ Hospital IRB #1):

U of Kentucky IRB #2 - Med Tuesday

C. Location of the IRB **20792**

*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):

322 Bosomworth Health Science Research Building

*City: **Lexington** *State/Province **KY** *Zip/Postal Code: **40536-0305**

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

*Phone: **859 257-8295** *FAX: **859 257-9700** *E-Mail: **aliten@email.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): **297**

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): **82**

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 products	other

Specify:

H. IRB Chairperson

*First Name: **Thomas** Middle Initial: *Last Name: **Foster**
Earned Degree(s): **Pharm.D.** Title or Position: **Professor, Executive Chair**

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

University of Kentucky
c/o Office of Research Integrity

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Member Name (Last, First)	Sex M/F	Earned Degree(s)	Scientist (S) or Non-scientist (N)	Primary Scientific or Non-Scientific Specialty	Affiliation with Institution(s) Y/N	Comments
Foster, Thomas	M	Pharm.D	Y	Pharmacology	Y	Other Scientist, exp 08/31/12
Hirschowitz, Edward	M	MD	Y	Pulmonary Oncology	Y	Physician Scientist, Vice Chair, VA Rep, exp 08/31/11
Holtman, Joe	M	MD, PhD	Y	Anesthesiology	Y	Physician Scientist, exp 08/31/10
White, Carol	F	MPH	Y	Epidemiology	Y	Other Scientist, exp 08/31/10
Walker, Robert	M	MSW, LCSW, M.Div	Y	Social Work	Y	Social Scientist, Prisoner Rep, exp 08/31/12
Whayne, Thomas	M	MD	Y	Cardiology	Y	Physician Scientist, exp 08/31/12
Skaff, Karen	F	PhD	Y	Higher Education	Y	Social Scientist, exp 08/31/12
Spiker, James	M	MS	N	Colonel US Army (Retired)	N	Nonscientist, Community Member, exp 08/31/11
Zink, Kathryn	F	RN, BSN	Y	Staff Development	Y	Social Scientist, VA Rep, exp 08/31/11
Shook, Lori	F	MD	Y	Pediatrics	Y	Physician Scientist, Vice Chair, Childrens Advocate, exp 08/31/11
Wilson, George	M	N/A	N	Business	N	Nonscientist, Community Member, exp 08/31/11

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.

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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: **IORG0000250**

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No, this is a new IRB registration.

B. Provide the IRB name, if any, used by the institution or organization (e.g., State University Behavioral IRB, University Healthcare Biomedical IRB, or XYZ Hospital IRB #1):

U of Kentucky IRB #3 - Med Thursday

C. Location of the IRB **20793**

*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):

322 Bosomworth Health Science Research Building

*City: **Lexington** *State/Province **KY** *Zip/Postal Code: **40536-0305**

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

*Phone: **859 257-8295** *FAX: **859 257-9700** *E-Mail: **aliten@email.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): **297**

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 **82**

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**

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

Specify:

H. IRB Chairperson

*First Name: **Thomas** Middle Initial: *Last Name: **Foster**
Earned Degree(s): **Pharm.D.** Title or Position: **Professor, Executive Chair**

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

University of Kentucky
C/o Office of Research Integrity

*City: **Lexington** *State/Province **KY** *Zip/Postal Code: **40506-0057**
University of Kentucky
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Member Name (Last, First)	Sex M/F	Earned Degree(s)	Scientist (S) or Non-scientist (N)	Primary Scientific or Non-Scientific Specialty	Affiliation with Institution(s) Y/N	Comments
Foster, Thomas	M	Pharm.D	Y	Pharmacology	Y	Other Scientist, exp 08/31/12
Hahn, Ellen J.	F	RN, DNS	Y	Drug Prevention	Y	Social Scientist, exp 08/31/11
Holleman, Donald	M	MD	Y	Internal Medicine	Y	Physician Scientist, VA Rep, exp 08/31/11
Malone, Terry	M	EdD	Y	PT Assessment	Y	Other Scientist, Vice Chair, exp 08/31/11
Rice, Linda	F	RN	Y	Nursing	Y	Other Scientist, exp 08/31/10
Thornton, Alice	F	MD	Y	Infectious Diseases	Y	Physician Scientist, exp 08/31/10
Tindall, Lyn	F	PhD	Y	Rehabilitation Sciences	Y	Other Scientist, VA Rep, exp 08/31/12
Damm, Douglas	M	DDS	Y	Dental Pathology	Y	Other Scientist, exp 08/31/10
Harper, Lee	M	N/A	N	Business	N	Nonscientist, Community Member, exp 08/31/11
Lain, Kristine	F	MD	Y	Obstetrics /Gynecology, Maternal-Fetal M	Y	Physician Scientist, Children's Advocate, exp 08/31/12

Alternative Members

NOTES:

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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 & Dept VAMC-Facility 596 IRB #6 - Med Wednesday

C. Location of the IRB **20795**

*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):

322 Bosomworth Health Science Research Building

*City: **Lexington** *State/Province **KY** *Zip/Postal Code: **40536-0305**

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

*Phone: **859 257-8295** *FAX: **859 257-9700** *E-Mail: **aliten@email.uky.edu**

D. ♦Approximate number of full time equivalent positions devoted to the IRB's administrative activities: **4**

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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):

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

Specify:

H. IRB Chairperson

*First Name: **Thomas** Middle Initial: *Last Name: **Foster**
Earned Degree(s): **PHARM.D.** Title or Position: **Professor, Executive Chair**

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

University of Kentucky
c/o Office of Research Integrity

*City: **Lexington** *State/Province **KY** *Zip/Postal Code: **40506-0057**
University of Kentucky
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*Phone: **859 323-8532** *FAX: **859 323-1921** *E-Mail: **foster@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.

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Foster, Thomas	M	PHARM.D.	Y	Pharmacology	Y	Other Scientist, exp 08/31/12
Nelson, Bill	M	BS	N	Mathmatics	N	Nonscientist, Community Member, exp 08/31/11
Rush, Craig	M	PhD	Y	Behavioral Science	Y	Social Scientist, Vice Chair, exp 08/31/10
McClung, Jeffrey	M	PhD	Y	Exercise Physiology/Cardiac Rehab	Y	Other Scientist, exp 08/31/10
Perrine, William	M	BS	N	Chemical Engineer (Retired)	N	Nonscientist, Community Member, exp 08/31/11
Yepes, Juan	M	DDS, MD, MPH	Y	Oral Health Practice	Y	Physician Scientist, Other Scientist, exp 08/31/10
Fleischman, Roger	M	MD	Y	Hematology/Oncology	Y	Physician Scientist, VA Rep, exp 08/31/10
Kanungo, Shibani	F	MD, MPH	Y	Pediatrics	Y	Physician Scientist, Childrens Advocate, exp 08/31/10
Duke, Mary	F	MD	Y	Geriatrics, Pediatrics, Pathology	Y	Physician Scientist, Decisionally Impaired, Children Adv., VA Rep, exp 08/31/11
Yannelli, John	M	PhD	Y	Immunotherapy	Y	Other Scientist, exp 08/31/11

Alternative Members

NOTES:

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