

INSTITUTIONAL REVIEW BOARD

INTRODUCTION

INTRODUCTION TO THE IRB REVIEW MECHANISM

In accordance with federal and institutional regulations, any undertaking in which a University faculty, staff or student investigates and/or collects data on human subjects for research purposes must be reviewed by either the Medical or Nonmedical Institutional Review Board (IRB). It is the responsibility of each investigator to seek review of any study involving human subjects prior to initiation of the project.

The Medical and Nonmedical IRBs are charged with the institutional responsibility for assurance of protection of human subjects involved in research or related activities. The Medical IRB reviews research emanating from the Colleges of Dentistry, Health Sciences, Medicine, Nursing, Pharmacy and Health Sciences, and Public Health. The Nonmedical IRBs review research originating from the Colleges of Agriculture, Arts & Sciences, Business & Economics, Communications & Information Studies, Design, Education, Engineering, Fine Arts, Law, and Social Work. The Boards have the authority to approve, require modifications to secure approval, or disapprove all human research activities overseen and conducted by the organization; to observe, or have a third party observe, the consent process; and to observe, or have a third party observe, the conduct of the research; to suspend or terminate approval of research that is not conducted in accordance with IRB requirements or that has resulted in unexpected serious harm to participants, even if previously approved. Also, in cases of noncompliance where corrective action is needed, IRB has the authority to issue appropriate sanctions including but not limited to requesting minor changes, determining data collected cannot be used for publication, suspending or terminating approval, disqualifying investigators from conducting research involving human subjects at the University, and recommending to University administration that further administrative action be taken.

Under federal regulations, an investigator's application to conduct a research project involving human subjects can be processed by the IRBs in three ways:

- by full review.
- by exemption certification;
- by expedited review;

The preliminary determination that a research project is eligible for exemption certification or expedited review is made by the investigator. Attached are the federally-mandated criteria which serve as a guide in making this determination. The categories eligible for exemption are listed on page 3; the expedited review criteria are on page 4-5.

The investigator should carefully review the attached information. Questions of interpretation may be directed to the Office of Research Integrity at 859-257-9428. After the type of review required for the project has been determined, the appropriate review application packet may be obtained from the Office of Research Integrity.

Also, included on the following pages is a list of the submission deadline dates and the meeting dates for the Medical and Nonmedical IRBs and a list of the members serving on the respective IRBs.

Finally, special instructions for investigators whose research is being submitted to or supported by an external funding agency are included on pages 14-16.

FULL REVIEWS

Research that cannot meet the criteria for exempt or expedited review must be submitted for full review.

Research activities in which the ONLY involvement of human subjects will be in one or more specified categories are eligible for exemption certification. Note, however, that the exemption categories do not apply when the research activities include the following:

- prisoners
- survey or interview techniques which include minors as subjects (this applies to exemption category #2 only)
- the observation of minors where the investigator participates in the activities being observed (this applies to exemption category #2 only)
- Food and Drug Administration (FDA) regulated research (this applies to exemption categories #1-5)

The categories of research activities eligible for exemption certification are as follows:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special educational instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category (b) of this section, if: the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. PLEASE NOTE: According to the Office for Human Research Protections (OHRP), "to qualify for this exemption, the data, documents, records, or specimens must be in existence before the project begins. The principle behind this policy is that the rights of individuals should be respected; subjects must consent to participation in research."
5. Research and demonstration projects which are conducted by or subject to the approval of department of agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; (iv) possible changes in methods or levels of payment for benefits or services under those programs; (v) projects for which there is no statutory requirement for IRB review; (vi) projects that do not involve significant physical invasions or intrusions upon the privacy interests of participants; (vii) authorization or concurrence by funding agencies that exemption from IRB review is acceptable.
6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome food without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

A description of the exemption certification procedures and a copy of the application form may be obtained by calling the Office of Research Integrity, 405 Kinkead Hall, 859-257-9084.

EXPEDITED REVIEW ELIGIBILITY REQUIREMENTS
Effective November 9, 1998

D47.0000

Applicability

- (A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
- (B) The categories in this list apply regardless of the age of subjects, except as noted.
- (C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- (D) The expedited review procedure may not be used for classified research involving human subjects.
- (E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.
- (F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

In addition, the IRB may also use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized.

Research Categories

- 1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- 2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - (a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - (b) From other adults and children¹ considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- 3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) Hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

- 4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echo-cardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- 5) Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
- 6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- 7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.)
- 8) Continuing review of research previously approved by the convened IRB as follows:
 - (a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - (b) Where no subjects have been enrolled and no additional risks have been identified; or
 - (c) Where the remaining research activities are limited to data analysis.
- 9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

A description of the expedited review procedures and a copy of the application form may be obtained from Joanne Hines, Office of Research Integrity, 306 Kinkead Hall, 859-257-9118.

¹ Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

MEDICAL INSTITUTIONAL REVIEW BOARD MEETING DATES
THE MEDICAL IRB MEETS WEEKLY; THERE ARE NO DEADLINE DATES. PROTOCOLS
SUBMITTED FOR REVIEW WILL BE PLACED ON THE NEXT AVAILABLE AGENDA.

Agendas are run approximately 10-14 days prior to a meeting

July 26, 2011- December 31, 2012

	<u>Meeting Date</u>	<u>Weekday</u>	<u>Meeting Place</u>	<u>Time</u>	<u>ORI Contact</u>
2011	July 26	Tuesday	410 Bosomworth HSRB	1:00pm	Roda Ferraro
	August 3	Wednesday	410 Bosomworth HSRB	1:15pm	Suzanne Arnold
	August 8	Monday	410 Bosomworth HSRB	1:00pm	Amy Kolasa
	August 11	Thursday	410 Bosomworth HSRB	1:15pm	Beverly Raisor
	August 16	Tuesday	410 Bosomworth HSRB	1:00pm	Roda Ferraro
	August 24	Wednesday	410 Bosomworth HSRB	1:15pm	Suzanne Arnold
	August 29	Monday	410 Bosomworth HSRB	1:00pm	Amy Kolasa
	September 1	Thursday	410 Bosomworth HSRB	1:15pm	Beverly Raisor
	September 6	Tuesday	410 Bosomworth HSRB	1:00pm	Roda Ferraro
	September 14	Wednesday	410 Bosomworth HSRB	1:15pm	Suzanne Arnold
	September 19	Monday	410 Bosomworth HSRB	1:00pm	Amy Kolasa
	September 22	Thursday	410 Bosomworth HSRB	1:15pm	Beverly Raisor
	September 27	Tuesday	410 Bosomworth HSRB	1:00pm	Roda Ferraro
	October 5	Wednesday	410 Bosomworth HSRB	1:15pm	Suzanne Arnold
	October 10	Monday	410 Bosomworth HSRB	1:00pm	Amy Kolasa
	October 13	Thursday	410 Bosomworth HSRB	1:15pm	Beverly Raisor
	October 18	Tuesday	410 Bosomworth HSRB	1:00pm	Roda Ferraro
	October 26	Wednesday	410 Bosomworth HSRB	1:15pm	Suzanne Arnold
	October 31	Monday	410 Bosomworth HSRB	1:00pm	Amy Kolasa
	November 3	Thursday	410 Bosomworth HSRB	1:15pm	Beverly Raisor
	November 8	Tuesday	410 Bosomworth HSRB	1:00pm	Roda Ferraro
	November 16	Wednesday	410 Bosomworth HSRB	1:15pm	Suzanne Arnold
	November 21	Monday	410 Bosomworth HSRB	1:00pm	Amy Kolasa
	November 29	Tuesday	410 Bosomworth HSRB	1:00pm	Roda Ferraro
	December 1	Thursday	410 Bosomworth HSRB	1:15pm	Beverly Raisor
	December 7	Wednesday	410 Bosomworth HSRB	1:15pm	Suzanne Arnold
	December 12	Monday	410 Bosomworth HSRB	1:00pm	Amy Kolasa
	December 20	Tuesday	410 Bosomworth HSRB	1:00pm	Roda Ferraro
2012	January 4	Wednesday	410 Bosomworth HSRB	1:15pm	Suzanne Arnold
	January 9	Monday	410 Bosomworth HSRB	1:00pm	Amy Kolasa
	January 12	Thursday	410 Bosomworth HSRB	1:15pm	Beverly Raisor
	January 17	Tuesday	410 Bosomworth HSRB	1:00pm	TBA
	January 25	Wednesday	410 Bosomworth HSRB	1:15pm	Suzanne Arnold
	January 30	Monday	410 Bosomworth HSRB	1:00pm	Amy Kolasa
	February 2	Thursday	410 Bosomworth HSRB	1:15pm	Beverly Raisor
	February 7	Tuesday	410 Bosomworth HSRB	1:00 pm	TBA
	February 15	Wednesday	410 Bosomworth HSRB	1:15pm	Suzanne Arnold
	February 20	Monday	410 Bosomworth HSRB	1:00pm	Amy Kolasa
	February 23	Thursday	410 Bosomworth HSRB	1:15pm	Beverly Raisor
	February 28	Tuesday	410 Bosomworth HSRB	1:00pm	TBA
	March 7	Wednesday	410 Bosomworth HSRB	1:15pm	Suzanne Arnold
	March 12	Monday	410 Bosomworth HSRB	1:00pm	Amy Kolasa
	March 15	Thursday	410 Bosomworth HSRB	1:15pm	Beverly Raisor
	March 20	Tuesday	410 Bosomworth HSRB	1:00pm	TBA
	March 28	Wednesday	410 Bosomworth HSRB	1:15pm	Suzanne Arnold
	April 2	Monday	410 Bosomworth HSRB	1:00pm	Amy Kolasa

April 5	Thursday	410 Bosomworth HSRB	1:15pm	Beverly Raisor
April 10	Tuesday	410 Bosomworth HSRB	1:00pm	TBA
April 18	Wednesday	410 Bosomworth HSRB	1:15pm	Suzanne Arnold
April 23	Monday	410 Bosomworth HSRB	1:00pm	Amy Kolasa
April 26	Thursday	410 Bosomworth HSRB	1:15pm	Beverly Raisor
May 1	Tuesday	410 Bosomworth HSRB	1:00pm	TBA
May 9	Wednesday	410 Bosomworth HSRB	1:15pm	Suzanne Arnold
May 14	Monday	410 Bosomworth HSRB	1:00pm	Amy Kolasa
May 17	Thursday	410 Bosomworth HSRB	1:15pm	Beverly Raisor
May 22	Tuesday	410 Bosomworth HSRB	1:00pm	TBA
June 6	Wednesday	410 Bosomworth HSRB	1:15pm	Suzanne Arnold
June 11	Monday	410 Bosomworth HSRB	1:00pm	Amy Kolasa
June 14	Thursday	410 Bosomworth HSRB	1:15pm	Beverly Raisor
June 19	Tuesday	410 Bosomworth HSRB	1:00pm	TBA
June 27	Wednesday	410 Bosomworth HSRB	1:15pm	Suzanne Arnold
July 9	Monday	410 Bosomworth HSRB	1:00pm	Amy Kolasa
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December 19	Wednesday	410 Bosomworth HSRB	1:15pm	Suzanne Arnold

*HSRB= Health Sciences Research Building

7/21/11

NONMEDICAL IRB DEADLINE AND MEETING DATES

ALL MATERIAL FOR INSTITUTIONAL BOARD REVIEW IS TO BE SUBMITTED
TO THE OFFICE OF RESEARCH INTEGRITY BY 5 P.M.
ON THE SPECIFIED DEADLINE DATE

NOTE: The Office of Research Integrity CLOSES at 5 p.m.

Proposals submitted after 5 p.m. on the deadline date will be scheduled for the next meeting. Due to our Computerized System, the deadlines will be adhered to strictly. For additional information, please contact the Office of Research Integrity at 859-257-1639.

*All Nonmedical IRB Meetings are held in **107 Breckinridge Hall***

DEADLINE DATES FOR SUBMISSION OF PROTOCOLS	*MEETING DATES* FOR REVIEW OF PROTOCOLS (Expedited and Full Review will be conducted at all of the following meetings.)
August 31, 2011	September 16, 2011
September 28, 2011	October 14, 2011
October 12, 2011	October 28, 2011
November 2, 2011	November 18, 2011
November 23, 2011	December 9, 2011
December 14, 2011	January 6, 2012
January 11, 2012	January 27, 2012
February 1, 2012	February 17, 2012
February 22, 2012	March 9, 2012
March 14, 2012	March 30, 2012
April 4, 2012	April 20, 2012
April 25, 2012	May 11, 2012
May 16, 2012	June 1, 2012
June 6, 2012	June 22, 2012
July 3, 2012	July 20, 2012
July 25, 2012	August 10, 2012
August 15, 2012	August 31, 2012

Updated 8/30/11

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): **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	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, Priscilla 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): **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	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): **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 **82**

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: **IRB00004367**

(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 #5 - Nonmedical Friday

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:

3

E. ♦Approximate number of all active protocols (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months):

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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:

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

human drugs	food additives
medical devices	color additives
biological	other
	Specify

H. IRB Chairperson

*First Name: **Norman** Middle Initial: *Last Name: **Van Tubergen**

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

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

c/o Office of Research Integrity

University of Kentucky

315 Kinkead Hall

315 Kinkead Hall

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

Country (if outside the U.S.):

*Phone: **859 257-8886** FAX: **859 257-8995** *E-Mail: **huc129@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
Van Tubergen, Norman	M	PhD	S	Communication	Y	Other Scientist, exp 8/31/14
Ford, Janet	F	PhD	S	Social Work	Y	Social Scientist, Vice Chair, exp 8/31/13
Langley, Ron	M	PhD	S	Political Science	Y	Social Scientist, Survey Research, exp 8/31/13
Flaherty, Chris	M	PhD	S	Social Work	Y	Social Scientist, exp 8/31/14
Gentry, William	M	BS	N	Business Management	N	Nonscientist, Community Member, exp 8/31/14
Levstik, Linda	F	PhD	S	Social Studies/Humanities	Y	Social Scientist, exp 8/31/14
Botto, Ron	M	PhD	S	Psychology	Y	Social Scientist, exp 8/31/13
Townley, Kimberly	F	PhD	S	Early Childhood Development	Y	Social Scientist, Childrens Advocate, exp 8/31/14
Vazsonyi, Alexander	M	PhD	S	Family Studies	Y	Social 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, Pediatics, 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.

The University of Kentucky's Institutional Review Boards (IRBs) and the Office of Research Integrity (ORI) are not directly involved in the grant/contract mechanism. The IRBs are University committees composed of faculty members who are appointed by the institution. The Boards are responsible for reviewing all research activities involving human subjects irrespective of the source of funding. Therefore, it is critical that an investigator who plans to submit a proposal to an external funding agency be familiar with the agency's and the University's policies regarding the certification of IRB review and approval.

Overview of Funding Agencies' Human Subject Certification Requirements

Most funding agencies (e.g., National Institutes of Health, Robert Wood Johnson Foundation, etc.) require that research projects involving human subjects be reviewed by an institutional review board prior to the submission of a grant/contract proposal. Formal certification that a research proposal has received the appropriate IRB approval must be sent to the agency.

The certification requirements vary from agency to agency. For example, some agencies have a special form or "item" on the application which must be completed by the applicant and signed by the University's Authorized Institutional Official. The designated official at this University is Debbie Davis, Director of the Office of Sponsored Projects Administration on behalf of Jack Supplee, Associate Director of the University of Kentucky Research Foundation. Other agencies accept the University's Institutional Review Board (IRB) approval letter which is signed by the IRB chairperson.

Agencies also differ with respect to their flexibility in accepting certification notices after the proposal has been received. For example, when submitting an application to the National Institutes of Health (NIH), it is critical that certification of approval be transmitted to the agency as soon as possible after the submission of the grant application. The grant application will not be reviewed if the certification document is not submitted before the Study Sections are convened. Other agencies may not require that certification be sent until the final decision with respect to funding status has been made. On the other hand, some agencies will not accept an application unless IRB certification is included. Questions regarding agency IRB certification policies should be directed either to the individual agencies or to the Office of Sponsored Projects Administration staff.

University Certification Procedures

In the past, problems between investigators, the IRB and Sponsored Projects Administration have arisen because of confusion with respect to the responsibilities of the various internal constituencies. Consequently, an overview of the University of Kentucky's IRB certification procedures is included on the next page. Questions concerning these procedures should be directed to the Office of Research Integrity at 859-257-9428.

Initial Certification of Review

1. Whenever possible, the research project should be submitted to the IRB prior to submission of the grant/contract application to the agency. The investigator is responsible for submitting the project for IRB review in a timely fashion.
2. If, due to the time constraints of the investigator, the research project has not been submitted to or reviewed by the IRB at the date of submission of the grant application to the agency, then the investigator is responsible for submitting the project to the IRB as soon as possible. NOTE: Sponsored Projects Administration does not submit a protocol to the IRB; it is the investigator's responsibility to do so.
3. After final IRB approval has been obtained, it is the investigator's responsibility to submit the proper certification form to the sponsor. The investigator should contact the Office of Research Integrity, requesting that the certification document be prepared. The Office of Research Integrity will then prepare the form and obtain the authorizing official's signature. The investigator is responsible for transmitting the form to the agency.

Resubmission of Previously Rejected Grant Applications to Funding Agencies

1. In the event that a research project previously approved by the IRB is resubmitted to an external funding agency, the investigator is responsible for contacting the Office of Research Integrity to determine the current IRB status of the proposal before the grant application is submitted to the agency.
2. If IRB approval has not been obtained within the 12-month period preceding the agency's submission deadline, submission of a new application to the IRB is necessary. A new certification document cannot be issued until the IRB has reviewed the study in accordance with the regular review procedures.
3. If IRB approval has been obtained in the 12 months preceding the agency submission deadline, a new IRB application need not be submitted to the IRB, provided no changes have been made in the research activities which affect the human research subjects. The investigator is responsible for submitting: a) a letter to the IRB indicating that the revised application does not include modifications regarding the human subjects' participation; b) a revised GENERAL INFORMATION SHEET, if appropriate. The investigator must request that the Office of Research Integrity prepare the certification document, as specified by the funding agency.
4. If the revised grant application includes changes which affect the human subjects, submission of a new application to the IRB is not necessary, provided the previously reviewed study had received IRB approval in the 12 months preceding the agency deadline. The investigator is required, however, to submit to the IRB the following: a) a revised GENERAL INFORMATION SHEET; b) a description of the proposed changes; c) revised consent and/or assent form; d) a revised copy of the grant application. Instructions for submitting a request for approval of modifications may be obtained from the Office of Research Integrity.

After the proposed modifications have been approved by the IRB, the investigator should contact the Office of Research Integrity, requesting that the certification document be prepared. The investigator is responsible for transmitting the form to the agency.

Rejected Grant Proposals: No Plans for Resubmission or Implementation of Research

If the grant proposal is rejected and if the investigator does not intend to implement the research project, the investigator should notify the Office of Research Integrity so that the file may be appropriately closed out.

Externally Funded Projects: Annual Recertification Procedures

Most funding agencies require that funded research projects involving human subjects receive a Continuation Review by the IRB at least once every 12 months. The agencies also require that an updated certification document be submitted at specified intervals. The Office of Research Integrity cannot provide an updated certification document unless the project has been reviewed and approved in accordance with the University's Continuation Review procedures.

The investigator is responsible for completing, at specified intervals, a Continuation Review Report form. A complete description of the IRB's Continuation Review procedures may be obtained from the Office of Research Integrity at 859-257-3038.

Once IRB approval of the Continuation Review report has been obtained, the investigator should contact the Office of Research Integrity, requesting that the recertification document be prepared. The investigator is responsible for transmitting the certification to the agency.

"Umbrella" Grant Certification

To prepare a certification form (HHS 310) for those grants/contracts which fund more than one IRB protocol, the Principal Investigator must provide the Office of Research Integrity with a list of IRB numbers which apply to that particular grant/contract. These numbers will be cross-checked by the Office of Research Integrity for approval before certification is issued. Once IRB approval has been verified, the appropriate documentation will be prepared. The investigator is responsible for transmitting the certification to the agency.