

IORG #: **IORG0000345**
Institution: **U of Arkansas for Med Sciences**
Expires: **08/27/2012**

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? IORG0000345

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 Arkansas for Med Sciences**

*Mailing Address: **4301 W. Markham
MS 636**

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

**4th & Jack Stephens
Rm B102**

*City: **Little Rock**

*State/Province **AR**

*Zip/Postal Code: **72205**

*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: **L**

Middle Initial: **D** *Last Name: **Milne**

Earned Degree(s): **Ph.D.**

Title or Position: **Vice Chancellor, Academic Affairs & Research
Admin**

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

**4301 West Markham Street, Mail Slot 541
MS 636**

*City: **Little Rock**

*State/Province **AR**

*Zip/Postal Code: **72205**

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

*Phone: **501 686-5672**

*FAX: **501 686-8137**

*E-Mail: **milnelarryd@uams.edu**

5. Contact Person Providing this Registration Information

*First Name: **Beth**

Middle Initial: **P** *Last Name: **Scanlan**

Earned Degree(s): **M.A.P.**

Title or Position: **IRB Assistant Director**

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

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

**4301 W. Markham
MS 636**

*City: **Little Rock**

*State/Province **AR**

*Zip/Postal Code: **72205**

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

*Phone: **501 526-6245**

*FAX: **501 686-7265**

*E-Mail: **bscanlan@uams.edu**

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

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

Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: **IRB00000593**

(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 Arkansas for Med Sciences IRB #1 (Biomedical 3rd Week)

C. Location of the IRB

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

**4301 W. Markham
MS 636**

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

4301 W. Markham

*City: **Little Rock**

*State/Province **AR**

*Zip/Postal Code: **72205**

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

*Phone: **501 526-6245**

*FAX: **501 686-7265**

*E-Mail: **bscanlan@uams.edu**

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

8

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):

1450

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):

300

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: **445**

‡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: **Louanne** Middle Initial: *Last Name: **Lawson**
Earned Degree(s): **Ph.D.** Title or Position: **Chairperson, IRB #1 (Biomedical 3rd Week)**

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

**Assistant Professor College of Nursing
4301 W. Markham MS 529**

*City: **Little Rock** *State/Province **AR** *Zip/Postal Code: **72205**

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

*Phone: **501 661-7901** *FAX: **501 686-8350** *E-Mail: **lawsonlouanne@uams.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
Lawson, Louanne	F	Ph.D.	Y	Nursing	Y	
Ilyas, Mohammad	M	MD	Y	Pediatric Nephrology	Y	Pediatrics
Tak, Sunghee	F	PhD	Y	Nursing	Y	
Hester, Micah	M	PhD	Y	Philosophy Med Humanities	Y	Pediatrics
May, Ron	M	LLB	N	Law	N	
Kuc, Eugene	M	MD	Y	Psychiatry	Y	CAVHS
Scott, Elaine	F	MA	N	English	Y	Affiliated with UALR
Wood, Linda	F	RN	Y	Otolaryngology	Y	
Beranek, David	M	Ph.D.	Y	Biochemistry	Y	NCTR
Mehta, Paulette	F	MD	Y	Hematology/Oncology	Y	Pediatrics
Hathaway, Betty	F	PhD	Y	Education	Y	UALR
Kleiner, Jennifer	F	PhD	Y	Psychology	Y	
Peck, Joyce	F	N/A	N	Business	N	
Alternative Members						
Holeman, Kethel	M	MS	Y	Psychology	N	Non-affiliated alternate or Prisoner Advocate as needed. Psych. Examiner with A
Fulk, Marion	F	AB	N	Finance	N	Non-scientist or Non-affiliated alternate
Solomon, Barry	M	MBA	N	Management	N	Non-scientist or non-affiliated alternate
Schriner, Byron	M	MBA	N	Finance	N	Non-scientist or non-affiliated alternate
Wohlleb, James	M	MS	Y	Public Health	Y	Vice-Chair
Eisenach, Kathleen	F	PhD	Y	Microbiology	Y	Alternate for Chair
Mahadevan, Mahendran	M	PhD	Y	OB/GYN	Y	Alternate for Chair
Killebrew, Pamela	F	BSN, RN	Y	Pediatrics Anesthesiology	Y	Alternate for pediatric representative 39
Walter, Donnal	M	MD, PhD	Y	Pediatric Neonatology	Y	Alternate for Peds: 39
Howard, Lee	F	RN	Y	Pediatrics	Y	Alternate for Peds: 39

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: **IRB00000742**

(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 Arkansas for Med Sciences IRB #2 (Biomedical 1st Week)

C. Location of the IRB

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

**4301 W. Markham
MS 636**

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

4301 W. Markham

*City: **Little Rock**

*State/Province **AR**

*Zip/Postal Code: **72205**

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

*Phone: **501 526-6245**

*FAX: **501 686-7265**

*E-Mail: **bscanlan@uams.edu**

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

8

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):

1450

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):

300

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: **445**

‡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: **Louanne** Middle Initial: *Last Name: **Lawson**
Earned Degree(s): **Ph.D.** Title or Position: **Chairperson, IRB #2 (Biomedical 1st Week)**

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

**Assistant Professor College of Nursing
4301 W. Markham MS 529**

*City: **Little Rock** *State/Province **AR** *Zip/Postal Code: **72205**

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

*Phone: **501 661-7901** *FAX: **501 686-8350** *E-Mail: **lawsonlouanne@uams.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
Lawson, Louanne	F	Ph.D.,	Y	Nursing	Y	
Wood, Linda	F	RN	Y	Otolaryngology	Y	
Fulk, Marion	F	AB	N	Finance	N	Non-scientist or Non-affiliated
Walter, Donnal	M	MD, PhD	Y	Pediatrics - Neonatology	Y	Pediatrics
Schrive, Byron	M	MBA	N	Finance	N	
Mason, Scott	F	N/A	N	N/A	N	
Yi, Richard	M	PhD	Y	Psychology/Behavioral Studies	Y	
Feild, Charles	M	MD	Y	Community Pediatrics	Y	Pediatrics
Borrelli, Michael	M	PhD	Y	Radiology	Y	
Gatling, Jeff	M	NA	Y	Oncology Research Administration	Y	
Beranek, David	M	Ph.D.	Y	Biochemistry	Y	Affiliated with NCTR
May, Ron	M	LLB	N	Law	N	
White, Jennifer	F	BSN, RN	Y	Anesthesiology/Pain Mgt	Y	
Alternative Members						
Holeman, Kethel	M	MS	Y	Psychology	N	Non-affiliated alternate; Prisoner advocate as needed. Psych. Examiner AR DOC
Scott, Elaine	F	MA	N	English	Y	Affiliated with UALR; Non-Scientific Alternate
Solomon, Barry	M	MBA	N	Management	N	Non-scientist or non-affiliated alternate
Peck, Joyce	F	N/A	N	Business	N	Non-scientist or non-affiliated alternate
Killebrew, Pam	F	BSN, RN	Y	Pediatric Anesthesiology	Y	Alternate for pediatric representatives 19, 23
Saylor, Robert	M	MD	Y	Hematology-Oncology - Pediatrics	Y	Alternate for pediatric representatives 19, 23
Long, Nicholas	M	PhD	Y	Pediatric Psychology	Y	Alternate for pediatric representatives 19, 23
Wohlleb, James	M	MS	Y	Public Health	Y	Vice-Chair
Eisenach, Kathleen	F	PhD	Y	Microbiology	Y	Alternate for Chair
Mahadevan, Mahendran	M	PhD	Y	OB/GYN	Y	Alternate for Chair
Gubbins, Paul	M	Pharm.D	Y	Pharmacy	Y	Alternate for Chair
Howard, Lee	F	RN	Y	Pediatrics	Y	Alternate for Peds: 19
Ilyas, Mohammad	M	MD	Y	Pediatric Nephrology	Y	Alternate for Peds: 19

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: **IRB00000745**

(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 Arkansas for Med Sciences IRB #3 (Biomedical 4th Week)

C. Location of the IRB

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

**4301 W. Markham
MS 636**

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

4301 W. Markham

*City: **Little Rock**

*State/Province **AR**

*Zip/Postal Code: **72205**

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

*Phone: **501 526-6245**

*FAX: **501 686-7265**

*E-Mail: **bscanlan@uams.edu**

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

8

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):

1450

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):

300

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: **445**

‡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: **Mahendran** Middle Initial: *Last Name: **Mahadevan**
Earned Degree(s): **Ph.D.** Title or Position: **Chairperson, IRB #3 (Biomedical 4th Week)**

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

Associate Professor of Obstetrics and Gynecology
4301 West Markham

*City: **Little Rock** *State/Province **AR** *Zip/Postal Code: **72205**

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

*Phone: **501 686-6359** *FAX: *E-Mail: **mahadevanmahendran@uams.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
Mahadevan, Mahendran	M	Ph.D.	Y	OB/GYN	Y	
Greene, Paul	M	PhD	Y	Health Behavior/Health Education	Y	
May, Ron	M	LLB	N	Law	N	
Saylors III, Robert	M	MD	Y	Hematology-Oncology - Pediatrics	Y	
Sherman, Allen	M	Ph.D.	Y	Behavioral Medicine	Y	
Murry, Carol	F	RN, BSN	Y	Critical Care Nursing	Y	
Chowdhurry, Parimal	M	Ph.D.	Y	Immunochemistry/Physi ology	Y	
Killebrew, Pam	F	BSN, RN	Y	Pediatrics Anesthesiology	Y	
Hackler, Chris	M	PhD	Y	Medical Humanities/Ethics	Y	
Jones, Cleve	M	N/A	N	N/A	N	
Miller, Harvey	M	PhD	Y	Physiology	Y	
Mills, Barbara	F	BSN	Y	Nursing	N	
Alternative Members						
Scott, Elaine	F	MA	N	English	Y	Affiliated with UALR; Non Scientific Alternate
Holeman, Kethel	M	MS	Y	Psychology	N	Non-affiliated alternate; Prisoner Advocate - Examiner with AR DOC
Fulk, Marion	F	AB	N	Finance	N	Non-scientist or Non-affiliated alternate
Hester, Micah	M	PhD	Y	Philosophy Medical Humanities	Y	Alternate for Dr Chris Hackler 19
Solomon, Barry	M	MBA	N	Management	N	Non-scientist or non-affiliated alternate
Peck, Joyce	F	N/A	N	Business	N	Non-scientist or non-affiliated alternate
Schriner, Byron	M	MBA	N	Finance	N	Non-scientist or non-affiliated alternate
Wohlleb, James	M	MS	Y	Public Health	Y	Vice-Chair
Lawson, Louanne	F	PhD	Y	Nursing	Y	Alternate for Chair
Eisenach, Kathleen	F	PhD	Y	Microbiology	Y	Alternate for Chair
Howard, Lee	F	RN	Y	Pediatrics	Y	Alternate for Peds member: 5, 11
Long, Nicholas	M	PhD	Y	Pediatric Psychology	Y	Alternates for Peds: 5, 13
Walter, Donnal	M	MD, PhD	Y	Pediatric Neonatology	Y	Alternate for Peds: 5, 13
Ilyas, Mohammad	M	MD	Y	Pediatric Nephrology	Y	Alternate for Peds: 5, 13

NOTES:

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

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

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

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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.

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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: **IRB00004852**

(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 Arkansas for Med Sciences IRB #5 - Biomed 2nd

C. Location of the IRB

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

**4301 W. Markham
MS 636**

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

4301 W. Markham

*City: **Little Rock**

*State/Province **AR**

*Zip/Postal Code: **72205**

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

*Phone: **501 526-6245**

*FAX: **501 686-7265**

*E-Mail: **bscanlan@uams.edu**

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

8

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):

1450

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):

300

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: **445**

‡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: **Kathleen** Middle Initial: *Last Name: **Eisenach**
Earned Degree(s): **Ph.D.** Title or Position: **IRB Chairperson IRB #5 (2nd week)**

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

Professor of Pathology
4301 W. Markham Street

*City: **Little Rock** *State/Province **AR** *Zip/Postal Code: **72205**

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

*Phone: **501 257-4827** *FAX: *E-Mail: **eisenachkathleend@uams.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
Eisenach, Kathleen	F	Ph.D.	Y	Microbiology	Y	
Solomon, Barry	M	MBA	N	Management	N	
Ferris, Ernest	M	MD	Y	Radiology	Y	
Yao-Borengasser, Aiwei	F	PhD	Y	Endocrinology	Y	
Cannon, Martin	M	PhD	Y	Microbiology	Y	
Gatling, Shelly	F	NA	Y	Oncology Research Administration	Y	
May, Ron	M	LLB	N	Law	N	
Hackler, Chris	M	Ph.D.	Y	Medical Humanities	Y	
Howard, Lee	F	RN	Y	Pediatrics	Y	Pediatrics
Alternative Members						
Holeman, Kethel	M	MS	Y	Psychology	N	Non-affiliated alternate or Prisoner Advocate as needed.
Fulk, Marian	F	AB	N	Finance	N	Non-scientist or Non-affiliated alternate
Hester, Micah	M	PhD	Y	Philosophy Med Humanities	Y	Alternate for Dr Chris Hackler 10
Scott, Elaine	F	MA	N	English	Y	NS alternate for Ron May - 5, UALR ties
Peck, Joyce	F	N/A	N	Business	N	Non-scientist or non-affiliated alternate
Schrivver, Byron	M	MBA	N	Finance	N	Non-scientist or non-affiliated alternate
Killebrew, Pam	F	BSN, RN	Y	Pediatric Anesthesiology	Y	Alternate for pediatric representatives 12, 33
Wohlleb, James	M	MS	Y	Public Health	Y	Vice-Chair
Lawson, Louanne	F	PhD	Y	Nursing	Y	Alternate for Chair
Mahadevan, Mahendran	M	PhD	Y	OB/GYN	Y	Alternate for Chair
Ilyas, Mohammad	M	MD	Y	Pediatric Nephrology	Y	Alternate for Peds: 12, 33
Walter, Donnal	M	MD	Y	Pediatric Neonatology	Y	Alternate for Peds: 12, 33
Saylors, Robert	M	MD	Y	Pediatric Hematology	Y	Alternate for Peds: 12, 33

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.

Public burden for this collection of information is estimated to average two hours for a new FWA filing and less than an hour for an FWA renewal or update. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: OS Reports Clearance Officer, Room 537H, 200 Independence Avenue, SW., Washington, DC 20201. Do not return the completed form to this address.