

Submission#: 22129
 IORG#: IORG0000303
 Institution: U of North Carolina at Chapel Hill

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? IORG0000303

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 North Carolina at Chapel Hill

*Mailing Address: **312 South Building**
CB # 4000

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

*City: **Chapel Hill** *State/Province **NC** *Zip/Postal Code: **27599-4000**

*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: **Tony** Middle Initial: **G** *Last Name: **Waldrop**
 Earned Degree(s): **Ph.D.** Title or Position: **Vice-Chancellor, Research and Economic Development**

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

Office of Research Services
312 South Building

CB# 4000

*City: **Chapel Hill** *State/Province **NC** *Zip/Postal Code: **27599-4000**

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

*Phone: **919 962-1319** *FAX: **919 962-1476** *E-Mail: **twaldrop@unc.edu**

5. Contact Person Providing this Registration Information

*First Name: **Carolyn** Middle Initial: *Last Name: **Mackman**
 Earned Degree(s): **BS, M.Phil.** Title or Position: **Compliance Coordinator, Office of Human Research Ethics**

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

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

105 Mason Farm Road
CB # 7097

*City: **Chapel Hill** *State/Province **NC** *Zip/Postal Code: **27599-7097**

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

*Phone: **919 843-8806** *FAX: **919 966-7879** *E-Mail: **cmackman@email.unc.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: **IORG0000303**

(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 North Carolina at Chapel Hill IRB #1 - Biomedical A

C. Location of the IRB **23687**

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

**105 Mason Farm Road
CB # 7097**

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

*City: **Chapel Hill**

*State/Province **NC**

*Zip/Postal Code: **27599-7097**

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

*Phone: **919 843-8806**

*FAX: **919 966-7879**

*E-Mail: **cmackman@email.unc.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):

615

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):

149

- 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: **64**

‡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: **David** Middle Initial: *Last Name: **Weber**

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

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

**Office of Human Research Ethics
105 Mason Farm Road
CB# 7097**

*City: **Chapel Hill** *State/Province **NC** *Zip/Postal Code: **27599-7097**

CB # 7097
*Country (if outside the U.S.):

*Phone: **919 966-3113** *FAX: **919 966-7879** *E-Mail: **dweber1@email.unc.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
Weber, David	M	MD	Y	Infectious Diseases/Epidemiology	Y	
Dressler, Lynn	F	Dr. PH	Y	Genetics and Bioethics	Y	
Surles, Jefferson	M	Pharm.D.	Y	Pharmacy	Y	
Whang, Young	M	MD	Y	Hem/Onc	Y	
Tielborg, Michael	M	MD	Y	Anesthesiology	Y	
Hammond, John	M	PhD	Y	Pathology	Y	
Hood, Ernie	M	MA	N	Communications	N	
Hudson-Barr, Diane	F	PhD, RN	Y	Newborn Critical Care	Y	
Edwards, Jr., Daniel David	M	Masters	Y	Prisoner Representative	N	Counts for quorum for subpart C only
Cancel, Aida	F	MS	Y	Reproductive Physiology	N	
Garbutt, James C.	M	MD	Y	Psychiatry	Y	
Kagarise, Mary Jane	F	MSPH, RN	Y	Nursing, Allied Health	Y	
Lea, James	M	PhD	N	International Research	Y	
Walters, Bradford B.	M	MD, PhD	Y	Surgery	N	

Alternative Members

Griese, Barbara		F	N/A	Not Specified	Y	May alternate, as appropriate, on all registered IRBs.
Tegnell, David		M	MA	Not Specified	Y	May alternate, as appropriate, on all registered IRBs.
Skrzynia, Cecile		F	MS	Genetic Counseling	Y	May alternate, as appropriate, on all registered IRBs.
Towle, Diane		F	BS, RN	Nursing	Y	May alternate, as appropriate, on all registered IRBs.
Richman, Erica		F	MSW	Developmental Disabilities	Y	May alternate, as appropriate, on all registered IRBs.
Stonerock, Gregory		M	BA	Psychology	Y	May alternate, as appropriate, on all registered IRBs.
Walton, Susan		F	RN, BSN	Oncology Nurse	Y	(Alt. Chair), May alternate, as appropriate, on all registered IRBs.
Birkhead, Tamar		F	JD	Criminal Law	Y	May alternate, as appropriate, on all registered IRBs.
Schreiner, Robert		M	MS	Not Specified	Y	May alternate, as appropriate, on all registered IRBs.
Loechner, Karen		F	MD	Pediatric Endocrinology	Y	May alternate, as appropriate, on all registered IRBs.
Rennie, Stuart		M	PhD	Philosophy, Ethics	Y	May alternate, as appropriate, on all registered IRBs.
Hamlett, Joyce		F	AAS	Not Specified	Y	May alternate, as appropriate, on all registered IRBs.
Farmer, Jennifer		F	MPH	Healthcare Administration	Y	May alternate, as appropriate, on

Goldman, Barbara	F	PhD	Developmental Psychology	Y	all registered IRBs. May alternate, as appropriate, on all registered IRBs.
Hoefges, Michael	M	JD, PhD	Mass Communication, Law and Policy	Y	May alternate, as appropriate, on all registered IRBs.
Austin, Dorcas	F	BS	Business	Y	May alternate, as appropriate, on all registered IRBs.
Zajac, David	M	PhD	Speech Pathology	Y	May alternate as appropriate on all registered IRBs.

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: **IORG0000303**

(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 North Carolina at Chapel Hill IRB #2 - Biomedical B

C. Location of the IRB **23688**

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

**105 Mason Farm Road
CB # 7097**

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

*City: **Chapel Hill**

*State/Province **NC**

*Zip/Postal Code: **27599**

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

*Phone: **919 843-8806**

*FAX: **919 966-7879**

*E-Mail: **cmackman@email.unc.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): **615**

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): **149**

- 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: **64**

‡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: **Doug** Middle Initial: *Last Name: **Mann**

Earned Degree(s): **MD** Title or Position: **Chair**

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

**105 Mason Farm Road
CB #7097**

*City: **Chapel Hill** *State/Province **NC** *Zip/Postal Code: **27599-7097**

CB # 7097
*Country (if outside the U.S.):

*Phone: **919 966-3113** *FAX: **919 966-7879** *E-Mail: **mannj@neurology.unc.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
Mann, Doug	M	MD	Y	Neurology	Y	
Savage, Scott	M	PharmD, MS	Y	Pharmacology	Y	
O'Neil, Bert	M	MD	Y	Oncology	Y	
Edwards, Jr., Daniel David	M	Masters	Y	Prisoner Representative	N	Counts for quorum for subpart C only.
Glover, Dianne	F	RN	Y	Nursing, Allied Health	Y	
Gold, Stuart H.	M	MD	Y	Oncology	Y	
Hammett-Stabler, Catherine	F	PhD	Y	Laboratory Science	Y	
Keyserling, Thomas C.	M	MD	Y	General Medicine	Y	
Yu, Bing	M	PhD	Y	Biomechanics	Y	
Girdler, Susan	F	PhD	Y	Psychology	Y	
Tyndall, Donald	M	DDS, PhD	Y	Dentistry; Radiation Physics	Y	
Rocamora, Nancy	F	BA	N	Not Specified	N	
Paquette, David	M	DMD, DMSc	Y	Periodontology	Y	
Winstanly, Louise	F	LLB	N	Bioethics	Y	
Friedman, Ina	F	RN, MSN, NP-C	Y	Cardiology/Critical Care/Nursing	Y	

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.

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: **IORG0000303**

(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 North Carolina at Chapel Hill IRB #5 - Public Health-Nursing

C. Location of the IRB **23689**

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

**105 Mason Farm Road
CB # 7097**

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

*City: **Chapel Hill** *State/Province **NC** *Zip/Postal Code: **27599-4000**

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

*Phone: **919 843-8806** *FAX: **919 966-7879** *E-Mail: **cmackman@email.unc.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): **615**

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 **102**

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 products	other
	Specify:

H. IRB Chairperson

*First Name: **Ruth** Middle Initial: *Last Name: **Humphry**

Earned Degree(s): **PhD** Title or Position: **Professor**

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

**105 Mason Farm Road
CB #7097**

*City: **Chapel Hill** *State/Province **NC** *Zip/Postal Code: **27599-7097**

CB # 7097
*Country (if outside the U.S.):

*Phone: **919 966-3113** *FAX: **919 966-7879** *E-Mail: **Ruth_Humphry@med.unc.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
Humphry, Ruth	F	PhD	Y	Allied Health	Y	
Strigo, Tara	F	MPH	Y	Population Science	Y	
Samuel-Hodge, Carmen	F	PhD, RD	Y	Nutrition; Chronic Disease	Y	
Bennett, Trude	F	PhD	Y	Maternal/Child Health	Y	Co-Chair
Edwards, Jr., Daniel David	M	Masters	Y	Prisoner Rep.	N	
Drane, JoAnne	F	MA	N	Education	N	
Lynn, Mary	F	PhD	Y	Administration & Finance; Pediatrics	Y	Alternate Chair
Zhou, Haibo	M	PhD	Y	Biostatistics	Y	
DeVellis, Brenda	F	PhD	Y	Psychology	Y	
Gammon, Marilie	F	PhD	Y	Epidemiology	Y	
Mayberry, April	F	BA	N	Clinical Investigator Liaison	N	
Knafl, Kathleen	F	PhD	Y	Family Management of Illness, Childhood	Y	
Benson, Mary Jane	F	Dr. P.H.	Y	Women's Reproductive Health and Rights	Y	
Ware, Andrea	F	MPH	Y	Environmental Exposure	N	

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.

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: **IORG0000303**

(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 North Carolina at Chapel Hill IRB #8 - Behavioral

C. Location of the IRB **23690**

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

**105 Mason Farm Road
CB # 7097**

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

*City: **Chapel Hill**

*State/Province **NC**

*Zip/Postal Code: **27599**

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

*Phone: **919 843-8806**

*FAX: **919 966-7879**

*E-Mail: **cmackman@email.unc.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): **615**

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 **39**

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 products	other
	Specify:

H. IRB Chairperson

*First Name: **Lawrence** Middle Initial: *Last Name: **Rosenfeld**

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

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

Behavioral IRB, Office for Human Research Ethics

CB# 3378, Bank of America Building

*City: **Chapel Hill** *State/Province **NC** *Zip/Postal Code: **27599-3378**

*Country (if outside the U.S.):
CB # 7097

*Phone: **919 962-7761** *FAX: **919 843-5576** *E-Mail: **aa-irb-chair@unc.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
Rosenfeld, Lawrence	M	Ph.D.	Y	Interpersonal Relationships	Y	
Ciocca, Mario	M	MD	Y	Internal Medicine	Y	
Kelly, Diane	F	PhD	Y	Information Science	Y	
Padua, Darin	M	PhD	Y	Athletic Training	Y	
Royster, Mark	M	PhD	N	Counseling	Y	
Parish, Susan	F	PhD	Y	Social Work; Poverty	Y	
Pungello, Elizabeth	F	PhD	Y	Child Development	Y	Co-Chair
Stone, Lynda	F	PhD	Y	Education	Y	
Youngstrom, Eric	M	PhD	Y	Psychology	Y	
Demers, B. Natalie	F	BS, MS, JD	N	Bioethics	N	
Dyar, Jessica	F	BS	N	IRB Administration	N	
Chapman, Mimi	F	PhD	Y	Child Welfare/Latino Immigrant Youth	Y	
Edwards, Daniel David	M	Masters	Y	Prisoner Representative	N	Counts for quorum for subpart C only

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.

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: **IORG0000303**

(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 North Carolina at Chapel Hill IRB #3 - Biomedical C

C. Location of the IRB **23691**

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

**105 Mason Farm Road
CB # 7097**

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

*City: **Chapel Hill** *State/Province **NC** *Zip/Postal Code: **27599-7097**

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

*Phone: **919 843-8806** *FAX: **919 966-7879** *E-Mail: **cmackman@email.unc.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): **615**

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 **149**

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: **64**

‡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: **Ina** Middle Initial: *Last Name: **Friedman**

Earned Degree(s): **MSN, RN** Title or Position: **Chair**

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

**105 Mason Farm Road
CB# 7097**

*City: **Chapel Hill** *State/Province **NC** *Zip/Postal Code: **27599-7097**

*Country (if outside the U.S.): **CB # 7097**

*Phone: **919 966-3685** *FAX: **919 966-7879** *E-Mail: **inafried@email.unc.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
Friedman, Ina	F	RN, MSN, NP-C	Y	Cardiology/Critical Care/Nursing	Y	
Tidwell, Rick	M	PhD	Y	Infectious Diseases	Y	
Bogges, Kim	F	MD	Y	Ob/Gyn	Y	
Kraybill, Ernest N.	M	MD	Y	Pediatrics	Y	
Collins, David	M	BS	N	Business	Y	
Dees, Claire	F	MD	Y	Oncology	Y	
Doughman, Renee	F	PhD	Y	Pharmacology	Y	
Garfinkel, Steven A.	M	PhD	Y	General Research	N	
Kagarise, Mary Jane	F	MSPH, RN	Y	Nursing, Allied Health	Y	
Pittman, A. Wayne	M	MS	Y	Pharmacy	Y	
Carbone, John	M	MD, JD, MBA	Y	Psychiatry, Prisoner Rep	N	
Shields, Jr, Edgar	M	PhD	Y	Exercise and Sport Science	Y	
Armstrong, Barbara	F	MA	N	Clergy	N	
Gangarosa, Lisa	F	MD	Y	Medicine/Gastroenterolo gy	Y	

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.

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: **IORG0000303**

(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 North Carolina at Chapel Hill IRB #4 - Biomedical D

C. Location of the IRB **23692**

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

**105 Mason Farm Road
CB # 7097**

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

*City: **Chapel Hill** *State/Province **NC** *Zip/Postal Code: **27599-7097**

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

*Phone: **919 843-8806** *FAX: **919 966-7879** *E-Mail: **cmackman@email.unc.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): **615**

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 **149**

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: **64**

‡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: **J. Herbert** Middle Initial: *Last Name: **Patterson**

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

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

Biomedical IRB, Office of Human Research Ethics

CB# 7097, Medical School Bldg 52

*City: **Chapel Hill** *State/Province **NC** *Zip/Postal Code: **27599-7097**

*Country (if outside the U.S.): **CB # 7097**

*Phone: **919 966-3113** *FAX: **919 966-7879** *E-Mail: **hpatterson@unc.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
Patterson, J. Herbert	M	Pharm.D.	Y	Pharmacy	Y	
Gold, Stuart H.	M	MD	Y	Oncology	Y	
Greenwood, Robert	M	MD	Y	Neurology	Y	
Kehrl, Howard	M	MD	Y	General Medicine	Y	
Perrin, Eliana Miller	F	MD, MPH	Y	Pediatrics	Y	
Weinstein, Diane	F	BA	N	Not Specified	N	
Bernard, Stephen A	M	MD	Y	Medicine/Oncology	Y	
Roche, Myra	F	MS	Y	Medical Genetics	Y	
Rakhra-Burris, Tejinder	F	MA	Y	Pharmacy/Business	Y	
Buchholz, Valerie	F	RN	Y	Nursing, Surgery	Y	
Land, Marjorie	F	not specified	N	Not Specified	Y	
Davenport, Marsha	F	MD	Y	Pediatric Endocrinology	Y	
Matthews, Robert	M	CRNA, MSNA	Y	Anesthesiology, Nursing	Y	
Edwards, Jr., Daniel David	M	Masters	Y	Prisoner Representative	N	Counts for quorum for subpart C only.

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.

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.

Do not return the completed form to this address.