Attachment #3: IRB Approvals

Attachment 3A: NCI-IRB Approval: Lung Case-Control Protocol
No: OH98-C-NO27

Attachment 3B: UMD-IRB Approval: Lung Case-Control Protocol
No: OH98-C-NO27

Attachment #3C: JHU-IRB Protocol Approval: Lung Case-Control Protocol
No: OH98-C-NO27

Attachment #3D: NCI-IRB Protocol Approval: Lung Case-Control Protocol
No: OH98-C-NO27

Attachment #3E: UMD-IRB Approval: Prostate Case-Control Protocol
No: 05-C-NO21 [01/05/02]

Attachment #3F: NCI-IRB Approval: Liver Case Control Protocol
No. 09-C-N149 [05/12/09]

Attachment #3G: UMD-IRB Approval: Liver Case-Control Protocol
No: 05-C-NO21 [01/05/02]

Attachment #3H: Baltimore Veteran's Admin – IRB approval

4/29/08

CLINICAL RESEARCH PROTOCOL CONTINUING REVIEW APPLICATION	PROTOCOL NO. OH98-C-N027	PRINCIPAL INVESTIGATOR (NIH Employee Name, Inst/Br, Address, Telephone and email): Elise Bowman NCI/LHC 37/3064 301-496-2090 bowmane@mail.nih.gov

PROTOCOL TITLE:

DNA Repair, p53 and Apoptosis Phenotypes in Lung Cancer

PROTOCOL STATUS:

- ☐ Renew -Recruitment of participants has not yet begun.
- ☒ Renew -Participants are currently being recruited or enrolled.
- ☐ Renew -No longer recruiting or enrolling participants, subject follow-up only.
- ☐ Renew -Participants have completed study, study and data analysis ongoing.
- ☐ Renew -Clinical Hold/Recruitment or enrollment of participants suspended.
- ☐ Terminate -Study closed. Participants have completed study. Recruitment and data analysis complete.

SUMMARY OF PROTOCOL ENROLLMENT (Aggregate) - Only when the NIH is the coordinating site, provide totals and enrollment data for all sites.

NIH Site	Other Sites	Total	
	3000	3000	Accrual ceiling by IRB
	232	232	New subjects enrolled since last CR
	2153	2153	Aggregate total accruals

Are you currently recruiting healthy volunteers? ☐ No ☒ Yes

Will the protocol involve adults unable to give informed consent? ☒ No ☐ Yes

Have analyses by sex, racial/ethnic subgroups been conducted for Phase 3 Clinical Trials as required? ☐ No ☐ Yes (answer a and b) ☒ N/A

a. Have analyses been reported? ☐ No (explain in narrative) ☐ Yes

b. Have significant differences been found? ☐ No ☐ Yes

Have any non-NIH investigators or sites been added since the last review?

- ☐ No
- ☒ Yes (Identify the persons or sites and describe the collaboration in the summary report)

WITH THIS REVIEW, I AM REQUESTING A CHANGE TO THE FOLLOWING:
*Include Name, Inst/Branch, Telephone, Address, e-mail. Check box if an NIH Employee and initial here. Attach sheets as necessary.

PRINCIPAL INVESTIGATOR:

Delete: ________

Add*: ☐ ________

EXTRAMURAL ADJUNCT PRINCIPAL INVESTIGATOR:

Delete: ________

Add: ________

MEDICAL ADVISORY INVESTIGATOR:

Delete: Elise Bowman

Add*: N/A

LEAD ASSOCIATE INVESTIGATOR:

Delete: ________

Add*: ☐ ________

RESEARCH CONTACT:

Delete: ________

Add*: ☐ ________

ASSOCIATE INVESTIGATOR(S):

Delete: ________

Add*: ☐ ________

IONIZING RADIATION USE (X-rays, e.g., CT, radioisotopes, e.g., PET, etc.) check all that apply

- ☒ None
- ☐ Medically indicated
- ☐ Research indicated. Since the last review,
  - ☐ Research usage HAS NOT changed.
  - ☐ Research usage HAS changed. (Explain in summary report)

INVESTIGATIONAL NEW DRUG/DEVICE ☒ None ☐ IND ☐ IDE
*If reporting more than one IND/IDE, list on attached sheet

FDA No: ________

Name: ________

Sponsor: ________

Who is the manufacturer of the above entity? ________

Does the protocol involve a Tech Transfer Agreement? ☒ No ☐ Yes

Does the protocol involve a drug/device/product that may lead to you or the NIH receiving payment and/or royalties?

- ☒ No
- ☐ Yes (Append a statement of disclosure)

Have there been any amendments since the last review?

- ☐ No
- ☒ Yes (Describe briefly in the attached narrative.)

Have there been any changes in the informed consent process or documentation since the last review?

- ☐ No
- ☒ Yes (Discuss in Summary report)

Have there been any changes in the subject population, recruitment or selection criteria since the last review?

- ☐ No
- ☒ Yes (Explain changes in the attached narrative.)

Have any unexpected complications or side effects been noted since the last review?

- ☒ No
- ☐ Yes (Identify and explain in the attached narrative.)

Have any subjects withdrawn from this study since the last IRB approval?

- ☐ No
- ☒ Yes (Discuss in the attached narrative.)

Has any information appeared in the literature, or evolved from this or similar research, that might affect the IRB's evaluation of the risk/benefit analysis of human subjects involved in this protocol?

- ☒ No
- ☐ Yes (Discuss in the attached narrative.)

Has the NIH IRP COI Guide been distributed to new NIH investigators?
☐ No ☐ Yes ☒ N/A

Has the NIH IRP COI Guide been distributed to new Non-NIH investigators?
☐ No ☐ Yes ☒ N/A

CONFLICTS OF INTEREST REVIEWS

Date submitted to IC DEC: 1/25/08 Date cleared by IC DEC: 2/19/08

	Signature	Print/Type Name	Date	
SIGNATURE	Elise D Bowman (Principal Investigator)	Elise Bowman	2/25/08	Send to Accountable Investigator
RECOMMENDATION	[signature] (Accountable Investigator)	~~Dr. Curtis Harris~~ Elise Bowman	2/24/08	Send to Branch Chief, or CC Dept. Head if Accountable Investigator
	[signature] (Br Chief/CC Dept. Head/Acct. Invest.)	Dr. Curtis Harris	2/24/08	Send to Clinical Director
APPROVALS	[signature] (Clinical Director)	F. Balis	4/10/08	Send to Chair, Institutional Review Board
	Maureen Hatch (Chair, Institutional Review Board)	Maureen Hatch	4/16/08 (Protocol & Consent Approved Effective)	Send to Office of Protocol Services through IRB Protocol Coordinator
COMPLETION	[signature] (Protocol Specialist)		4/21/08	

August 13, 2008

RAYMOND JONES
UNIVERSITY OF MARYLAND BALTIMORE
ANATOMIC PATHOLOGY

University of Maryland Baltimore
Office of Research Subjects
Phone: (410) 706-5037
Fax: (410) 706-4189
Email: hrpo@som.umaryland.edu

H-20678 - RESOURCE COLLECTION AND EVALUATION OF HUMAN TISSUES AND CELLS FROM DONORS WITH AN EPIDEMIOLOGY PROFILE FOR NCI CONTRACT # N02-RC-57700

APPROVAL VALID FROM 8/13/2008 TO 8/13/2009

Dear Dr. JONES

This is to certify that the Institutional Review Board for Human Subject Research at University of Maryland Baltimore has approved your research protocol.

Research activity involving veterans and/or the Baltimore VA Maryland Healthcare System (BVAMHCS) as a site, must also be approved by the BVAMHCS Research and Development Committee prior to initiation. Contact the VA Research Office at 410-605-7131 for assistance.

The study may not continue after the approval period without additional IRB review and approval for continuation. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

Any changes in study or informed consent procedure must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participants' safety or willingness to continue in your study.

The UMB IRB is organized and operated according to guidelines of the International Council on Harmonization , the United States Office for Human Research Protections and the United States Code of Federal Regulations and operates under Federal Wide Assurance No. FWA00007145

If the Investigational Drug Service is utilized for this research study, it is the principal investigator's responsibility to notify the IDS of all IRB-approved changes to this protocol that involve investigational agents.

Sincerely yours,

Robert Edelman, M.D.

Robert Edelman M.D.
IRB Chair

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Mir nil

JHSPH Institutional Review Board Office

6 i5 N. Wolfe Street I Suite El 100
Baltimore, Maryland 21205
Office Phone: (410) 955-3193
Toll Free: 1-888-262-3242
Fax Number: (410) 502-0584
E-mail Address: irbrifftelaihsph.edu
Website: www.hsph.eduhrb

FWA #00000287

AMENDMENT APPROVAL NOTICE

EXPEDITED REVIEW

Date: April 14, 2009

To: Rex Yung, MD
Department of Epidemiology

From: Elizabeth A. Skinner, MSW
Chair, IRB-X

Re: **Study Title:** "DNA Repair, p53 and Apoptosis Phenotypes in Lung Cancer"
IRB No: 98-06-05-07-2

The JHSPH IRB reviewed and approved your amendment request, dated **March 20, 2009,** described below, on **April 9, 2009.**

1. **Change the study PI from Manning Feinleib to Rex Young.**

2. **Add Edward Gabrielson as a co-investigator.**

3. **To change the Lung Cancer Case, Hospital Control, and Population Control Consent Forms to the new Biospecimen Consent Form Template and to revise the forms to include the change in PI,**

4. **To revise the HIPAA forms, Medical Record Release form, Case and Hospital Control Flyers to include the change in PI.**

This amendment approval is inclusive of the following documentation:

Consent Form-Population Controls (Version #1, 3/19/09)
Consent Form-Hospital Controls (Version #1, 3/19/09)
Consent Form-Lung Cancer Cases (Version #1, 3/19/09)
HIPAA Medical Records Release Form (3/19109)
Flyer Flyer HIPAA Authorization Form
(3/19/09)

University of Maryland Baltimore
Office of Research Subjects
Phone: (410) 706-2037
Fax: (410) 706-4109
Email: hrpo@som.umaryland.edu

MEMORANDUM

TO: RAYMOND JONES
ANATOMIC PATHOLOGY
FROM: Robert Edelman M.D.
IRB Chair

Robert Edelman, M.D.

DATE: August 30, 2004

RE: H-20678 - RESOURCE COLLECTION AND EVALUATION OF HUMAN TISSUES AND CELLS FROM DONORS WITH AN EPIDEMIOLOGY PROFILE

The IRB has approved the modification request detailed below.

Description:

The Laboratory of Human Carcinogenesis at The National Cancer Institute has been approved to conduct a case control study of Prostate Cancer. We are requesting an amendment to the current study because the Case Control Study of Lung Cancer and the new Prostate study are designed to work together. The population control group from the Case Control Study will be utilized in the Prostate study as well. This will be further illustrated in the following sections: C, D, F1, F3, F4, G1, G2, H, I, J1, J2, L, N and Section S. Also we would like to request certain changes to the subject's rights section of the following consent forms: Prostate Study Cases - VA, Prostate Study - UMMS, Population Controls - Male. The subject's rights changes for the consents are attached in section S. In addition we would like to request that the IRB change the study ID number #0298229 on the HIPAA waiver and the Authorization form form to the new BRAAN IRB number of H-20678.

4/20/09

CLINICAL RESEARCH PROTOCOL CONTINUING REVIEW APPLICATION	PROTOCOL NO. 05-C-N021	PRINCIPAL INVESTIGATOR (NIH Employee Name, Inst/Br, Address, Telephone and email) Stefan Ambs Ph.D., NCI, Bldg.37, Room 3050B, Bethesda, MD 20892-4258

PROTOCOL TITLE

A Case-Control Study of Prostate Cancer in the Greater Baltimore Area

PROTOCOL STATUS

- ☐ Renew -Recruitment of participants has not yet begun.
- ☒ Renew -Participants are currently being recruited or enrolled.
- ☐ Renew -No longer recruiting or enrolling participants, subject follow up only.
- ☐ Renew -Participants have completed study; study and data analyses ongoing.
- ☐ Renew -Clinical Hold/Recruitment or enrollment of participants suspended.
- ☐ Terminate -Study closed. Participants have completed study. Recruitment and data analysis complete.

SUMMARY OF PROTOCOL ENROLLMENT (Aggregate) Only when the NIH is the coordinating site, provide totals and attach table for all sites.

NIH Site	Other Sites	Total	
	1200	1200	Accrual ceiling by IRB
	178	178	New subjects accrued since last CR
	610	610	Aggregate total accrued

Are you currently recruiting healthy volunteers? ☐ No ☒ Yes

Will the protocol involve adults unable to give informed consent? ☒ No ☐ Yes

Have analyses by sex, racial/ethnic subgroups been conducted for Phase 3 Clinical Trials as required? ☐ No ☐ Yes (answer a and b) ☒ N/A

a. have analyses been reported? ☐ No (explain in narrative) ☐ Yes

b. have significant differences been found? ☐ No ☐ Yes

Have any non NIH investigators or sites been added since the last review?

☒ No

☐ Yes (Identify the persons or sites and describe the collaboration in the summary report)

WITH THIS REVIEW, I AM REQUESTING A CHANGE TO THE FOLLOWING:
Include Name, Inst/Branch, Telephone, Address, e-mail. Check box for NIH Employees and include their Agreement if necessary.

PRINCIPAL INVESTIGATOR

Delete: ____

Add*: ☐ ____

EXTRAMURAL ADJUNCT PRINCIPAL INVESTIGATOR

Delete: ____

Add: ____

MEDICAL ADVISORY INVESTIGATOR

Delete: ____

Add*: ____

LEAD ASSOCIATE INVESTIGATOR

Delete: ____

Add*: ☐ ____

RESEARCH CONTACT

Delete: ____

Add*: ☐ ____

ASSOCIATE INVESTIGATOR(S)

Delete: ____

Add*: ☐ ____

IONIZING RADIATION USE (X-rays, e.g. CT; radioisotopes, e.g. PET, etc.) check all that apply:

- ☒ None
- ☐ Medically indicated
- ☐ Research indicated – Since the last review
  - ☐ Research usage HAS NOT changed.
  - ☐ Research usage HAS changed. (Explain in summary report)

INVESTIGATIONAL NEW DRUG/DEVICE ☒ None ☐ IND ☐ IDE
If reporting more than one IND/IDE, list on attached sheet.

FDA No. ____

Name: ____

Sponsor: ____

Who is the manufacturer of the above entity? ____

Does the protocol involve a Tech Transfer Agreement? ☒ No ☐ Yes

Does the protocol involve a drug/device/product that may lead to you or the NIH receiving payment and/or royalties?

- ☒ No
- ☐ Yes (Append a statement of disclosure)

Have there been any amendments since the last review?

- ☒ No
- ☐ Yes (Describe briefly in the attached narrative)

Have there been any changes in the informed consent process or documentation since the last review?

- ☒ No
- ☐ Yes (Describe in Summary report)

Have there been any changes in the subject population, recruitment or selection criteria since the last review?

- ☒ No
- ☐ Yes (Explain changes in the attached narrative.)

Have any unexpected complications or side effects been noted since the last review?

- ☒ No
- ☐ Yes (Identify and explain in the attached narrative.)

Have any subjects withdrawn from this study since the last IRB approval?

- ☒ No
- ☐ Yes (Discuss in the attached narrative.)

Has any information appeared in the literature, or evolved from this or similar research, that might affect the IRB's evaluation of the risk/benefit analysis of human subjects involved in this protocol?

- ☒ No
- ☐ Yes (Discuss in the attached narrative.)

Has the NIH IRP COI Guide been distributed to new NIH investigators?
☐ No ☐ Yes ☒ N/A

Has the NIH IRP COI Guide been distributed to new Non-NIH investigators?
☐ No ☐ Yes ☒ N/A

CONFLICTS OF INTEREST REVIEW

Date submitted to IC DEC: 2/20/09 Date cleared by IC DEC: 2/26/09

	Signature	Print/Type Name	Date	
SIGNATURES	[signature] Principal Investigator	Stefan Ambs	2/23/2009	Send to Accountable Investigator
RECOMMENDATION	[signature] Accountable Investigator	Stefan Ambs	2/23/2009	Send to Branch Chief or Dept. Head of Accountable Investigator
	[signature] Br Chief/CC Dept. Head of Acct. Invest.	Curtis C. Harris	02/23/09	Send to Clinical Director
APPROVALS	[signature] Clinical Director	Lee Helman	4/7/09	Send to Chair, Institutional Review Board
	[signature] Chair, NIH Institutional Review Board	Nancy Potischman	4/7/09 Protocol & Consent Approval Effective	Send to Office of Protocol Services, through IRB Protocol Coordinator
COMPLETION	[signature] Protocol Specialist	Date 4/14/09		

CLINICAL RESEARCH
PROTOCOL **INITIAL** REVIEW

PRINCIPAL INVESTIGATOR (Name of NIH Employee, Institute/Branch, Address, Telephone and email):
Xin Wei Wang 301.496.2099 wangx@intra.nci.nih.gov 37 / 3044A

PROTOCOL TITLE: A STUDY OF MOLECULAR AND GENETIC FACTORS FOR LIVER CANCER IN THE GREATER BALTIMORE AREA

ABBREVIATED TITLE (30 characters or less): BIOMARKERS FOR LIVER CANCER Reference Number: 304698

PROPOSED START DATE: 07/01/2009 END DATE: 07/01/2014 TOTAL SUBJECTS TO *BE* ACCRUED (Attach target table for Phase 3-4): 1,250

MULTI-SITE COLLABORATION:
Is this a multi-site collaboration? El Yes (complete this section) ☐ No
Will subjects participate on the protocol at the NIH CC? ☐ Yes El No
VVIII subjects participate on the protocol at other sites? El Yes ☐ No
If yes, are the sites El Domestic ☐ Foreign ☐ Both
Is NIH the coordinating site?
Yes. For each participating site, provide: Institution name, address, investigator(s), indicate if subjects will be recruited and if they are, include a contact name on attached sheet/protocol face sheet.
☐ No. Coordinating Site is _____

REQUESTED ACCRUAL EXCLUSION (Check all that apply):
☐None
9 Male
Female
Children <18
☐ American Indian/Alaskan Native
Asian
Black or African American
White
Hispanic or Latino
Native Hawaiian or Pacific Islander

SUBJECT ACCRUAL CHARACTERISTICS:
Minimum Age Permitted 18
Maximum Age Permitted 90
Pediatric: El None☐ <2 Yr. ☐ 2-6 Yrs. ☐ 7-17 Yrs.
LEtr6'rocol involves healthy volunteers? El Yes ☐ No
Healthy Volunteers NIH Employees? ☐ Yes El No
Does the protocol permit self referral? ☐ Yes El No
Will the protocol involve adults unable to give informed consent? ☐ Yes El No

PROTOCOL TYPE: (Check one):
☐ Screening
☐ Training
☐ Natural History - Disease Progression/Physiology El
Natural History - Sample/Data Collection or Analysis (Recruiting Patients)
☐ Natural History - Sample/Data Collection or Analysis (Not Recruiting Patients)
☐ Pharmacokinetics/Dynamics
☐ Clinical Trial: Identify Phase (Check one)
☐ Phase 0 ☐ Phase 1 ☐ Phase 1-2
☐ Phase 2 ☐ Phase 3 ☐ Phase 4

If a Phase 3 Clinical Trial, is analysis for sex, racial/ethnic subgroups required according to the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research? ☐ Yes ☐ No IZ N/A

KEY WORDS (Words or phrase that describe the protocol.)
1 Liver Cancer
2 Hepatocellular Carcinoma
3 Chronic Liver Disease
4 Genome wide association study
5 Gene expression profiling

IONIZING RADIATION USE (X-rays, e.g., CT; radioisotopes, e.g. PET; etc.): check all that apply
E] None ☐ Medically indicated ☐ Research indicated*
* Complete NIH-08-23a, and attach to this application. Send a copy of entire protocol and NIH-08-23a to Chair, Radiation Safety for concurrent review.

INVESTIGATIONAL NEW DRUG/DEVICE: El None ☐ IND ☐ IDE
•If reporting more than one IND/IDE, list on attached sheet.
FDA No See attached page for IND / IDE information
Name' _____
Sponsor _____
Who is the manufacturer of the above entity? _____
Lpeigie protocol involve a Tech Transfer Agreement? ☐ Yes El No

Does the protocol involve a drug/device/product that may lead to you or the NIH receiving payment and/or royalties?
☐ Yes (Append a statement of disclosure)
El No

Has the NIH IRP COE Guide been distributed to NIH investigators?
Ej Yes ☐ No
Has the NIH IRP COE Guide been distributed to Non-NIH investigators?
E] Yes ☐ No ☐ N/A

CONFLICTS OF INTEREST REVIEW:
Date submitted to IC DEC: 12/15/2008 Date cleared by IC DEC 12/30/2008

Is an Extramural Investigator an ADJUNCT PRINCIPAL INVESTIGATOR ☐ Yes El No
Name of Adjunct PI

MEDICAL ADVISORY INVESTIGATOR (if necessary) Name, Inst/Branch, Telephone, Address, Email and initial line:

LEAP ASSOCIATE INVESTIGATOR - Name, Inst/Branch, Telephone, Address, Email. C,'ck box if an NIH employee and initial line
•4 Anuradha Budhu NCI LHC 301.496.5987 budhuaa

RESEARCH CONTACT: Name, Inst/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line:
☐ See attached personnel list

ASSOCIATE INVESTIGATOR(S): Name, Institute/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line. Attach list if necessary.
1☐ See attached personnel List
2. _____ 0
3. _____ 0
4. _____ 0

(Principal Investigator: Be sure to Include PRECIS <=400 words as first section of protocol)

SIGNATURE Xin Wang - applied signature on 05/11/2009 9:25 PM EDT — Principal Investigator — Print/Type Name — Date — Send to Accountable Investigator

RECOMMENDATION PI is the Accountable Investigator — Accountable Investigator — Print/Type Name — Date — Send to Branch Chief, or CC Dept. Head of Accountable Investigator

Curtis Harris, applied signature on 04/06/2009 1:51 PM EDT — Br. Chief/CC Dept. Head of Acct. Invest. — Print/Type Name — Date — Send to Institute/Center Scientific Review Committee

APPROVALS Caryn Steakley . applied signature on 05/12/2009 3:41 PM EDT — For Institute/Center Scientific Review Comm. — Print/Type Name — Date — Send to Clinical Director

Caryn Steakley, applied signature on 05/14/2009 8:10 AM EDT — Clinical Director — Print/Type Name — Date — Send to Chair, Institutional Review Board

Wanda Belzer - applied signature on 05/12/2009 9:30 AM EDT — Ch-4 4 1 ' stitutional Review Board — Print/Type Name — Date 5"/z e/IP 7 (DD/ MON/ YY) — Return to Offices of Protocol S

PATIENT SAFETY/ [illegible] COMPLETION — [illegible] 4 C Cay — Print/Type Name — Date — PROTOCOL NO. 09— e_ivig94,3 Meeting Date: 04/27/2009

[redacted] h-- or/67

Clinical Research Protocol Initial Review Application
NIH-1195 (9-06)

(88) FOS447

University of Maryland, Baltimore
Institutional Review Board (IRB)
Phone: (410) 706-5037
Fax: (410) 706-4189
Email: hrpo@som.umaryland.edu

Modification Approval Notification

Date: January 19, 2010

To: Dean Mann
From: IRB Chair/Vice Chair: Stephen Salyer
RE: HM-HP-00042,03-4
Risk designation: Minimal Risk
Modification request dated: 12/14/2009
Modification Approval Date: 1/19/2010
Protocol Version and ID #: N/A

This is to certify that the University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) has approved the above referenced modification request for the protocol entitled, "Resource Collection and Evaluation of Human Tissues and Cells from Donors with an Epidemiology Profile for NCI Contract: #N02-RC-57700".

Investigators are reminded that the IRB must be notified of any changes in the study or informed consent procedures. In addition, the PI is responsible for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103(4)(iii).

The UMB IRB is organized and operated according to guidelines of the International Council on Harmonization, the United States Office for Human Research Protections and the United States Code of Federal Regulations and operates under Federal Wide Assurance No. FWA00007145.

VA MARYLAND
HEALTH CARE SYSTEM
410-605-7000 ext 4528

VAMHCS Research and Development Office

Fax 410-605-7906

MEMORANDUM

To: **Dean Manu**
From: Christopher T. Bever, Jr., M.D., M.B.A. — Associate Chief of Staff for Research and Development
Leslie Katzel, MD — Chair, R&D Committee

Date: October 21, 2009
Re: Research and Development Committee Review
For **Initial** **X Continuing Review** **X Amendment**

IRB Number: HP00042163 (H20678)
Title: RESOURCE COLLECTION AND EVALUATION OF HUMAN TISSUES AND CELLS FROM DONORS WITH AN EPIDEMIOLOGY PROFILE FOR NCI CONTRACT # N02-RC-57700
IRB Approval Date: July 15, 2009 and amendments August 7, 2009 and September 23, 2009

This is to notify you that on August 27, 2009 the VA Research and Development Committee (RDC) conditionally approved your protocol. As of October 21, 2009 the conditions have been satisfied and your protocol is approved.

- Destruction of data timeline has changed! **Please read the Hot Topic available at: http://www.maryland.research.va.gov/hot_topics.asp**

Please read the following important instructions:

- It is the responsibility of the PI to upload this R&D approval letter into the BRAAN/CICERO system. Per Demian Lewis, BA, CIM, Program Manager, IRB Operations: *VA R&D approval letters can be attached in a public comment in CICERO. An amendment does not need to be submitted.*
- Effective September 2008, Principal Investigators are responsible for the oversight of VA educational and credentialing requirements for all study staff.
- Any changes made to the protocol requiring IRB notification or approval also needs VA Research and Development Committee notification and approval. You have 10 working days from the receipt of your IRB approval letter to submit your protocol to the R&D committee.

VA MARYLAND
HEALTH CARE SYSTEM

VAMHCS Research and Development Office

410-605-7000 ext 4528 Fax 410-605- 7906

MEMORANDUM

To: Dean Mann
From: Christopher T. Bever, Jr., M.D., M.B.A. Leslie Katzel, MD
Associate Chief of Staff for Research and Development Chair, R&D Committee

Date: November 13, 2009
Re: Research and Development Committee Review
For □ **Initial** □ **Continuing Review** **X Amendment #3**

IRB Number: HP00042163
Title: RESOURCE COLLECTION AND EVALUATION OF HUMAN TISSUES AND CELLS FROM DONORS WITH AN EPIDEMIOLOGY PROFILE FOR NCI CONTRACT # N02-RC-57700
IRB Approval Date: October 20, 2009

This is to notify you that on November 12, 2009 the VA Research and Development Committee (RDC) administratively approved your protocol.

- Destruction of data timeline has changed! **Please read the Hot Topic available at: http://www.maryland.research.va.gov/hottopics.asp**

Please read the following important instructions:

- It is the responsibility of the PI to upload this R&D approval letter into the BRAAN/CICERO system. Per Demian Lewis, BA, CIM, Program Manager, IRB Operations: *VA R&D approval letters can be attached in a public comment in CICERO. An amendment does not need to be submitted.*
- Effective September 2008, Principal Investigators are responsible for the oversight of VA educational and credentialing requirements for all study staff.
- Any changes made to the protocol requiring IRB notification or approval also needs VA Research and Development Committee notification and approval. You have 10 working days from the receipt of your IRB approval letter to submit your protocol to the R&D committee.