Attachment 4: NIH Clinical Exemption Approval

Email Message:
From: Tuttleman, Marilyn (NIH/OD) [E]
Sent: Wednesday, October 28, 2009 9:40 AM
To: Trivers, Glennwood (NIH/NCI) [E]
Subject: Approval of Blanket Clinical Exemption Request #2009-09-002

Follow Up Flag: Follow up
Flag Status: Red
To: Dr. Glenwood Trivers, NCI

This is in response to your request for a Blanket clinical exemption relating to the study entitled "Resource Contract for the Collection and Evaluation of Human Tissues and Cells from Donors with an Epidemiology Profile", as detailed below. The committee has determined the protocols proposed to be included under these contracts are clinically exempt, with the following comments:

> Per our phone conversation, please note that this approval is for information collection from the patients only. You cannot survey the DMV controls under this clinical exemption; collecting information from the DMV controls will require OMB approval.
>
> The link to the Project Clearance Branch website is http://odoerdb2.od.nih.gov/oer/policies/project_clearance/pcb.htm. Please see Information on Preparing a Package for Clearance for guidance on submitting a request. We are available to assist you should you have any questions.

If you should propose to do other protocols modifying the recruitment and randomization procedures under these contracts, you will need to submit those protocols for review by the Clinical Exemption Review Committee.

In addition, please forward a copy of each protocol activated under these contracts to odoperaclinicalexemp@mail.nih.gov for our records. Please be sure that all protocol and consent forms under these contracts include the following elements:

- Statement of Privacy Act applicability (reference Privacy Act System of Records Notice (SORN) # 09-25-0200 which covers clinical, basic and population-based research studies of the NIH).
- Citation of the appropriate statutory authorization for NIAID (42 CFE 281 (F)).
- If the research includes children, a reference to Title 45, Code of Federal Regulations, Part 46, Subpart D.

Please use this number in any future correspondence about any protocols under these contracts: #2009-09-002.

If you have any further questions, please contact me.

Regards,

Sherry Mills, MD MPH
Chair
Clinical Exemption Committee
Office of Extramural Research
OD/NIH/DHHS
One Center Drive
Building 1, Room 140
Bethesda, MD 20892

Note: This exemption pertains only to OMB review of the study. It does not exempt the study from any other relevant regulations (such as 45 CFR 46, Protection of Human Subjects, HIPAA or the Privacy Act)

Clinical Exemption Request Information

Exemption #:	**2009-09-002**
Exemption Type:	Blanket
Status:	**Approved** (10/28/2009)
	Emails previously sent for this Clinical Exemption: 09/15/2009-New_Exemption_Email -- 09/15/2009-Reviewer_Assignment_Email
	Approval Comments: Per our phone conversation, please note that this approval is for information collection from the patients only. You cannot survey the DMV controls under this clinical exemption; collecting information from the DMV controls will require OMB approval. The link to the Project Clearance Branch website is http://odoerdb2.od.nih.gov/oer/policies/project_clearance/pcb.htm. Please see Information on Preparing a Package for Clearance for guidance on submitting a request. We are available to assist you should you have any questions.
Title:	**Resource Contract for the Collection and Evaluation of Human Tissues and Cells from Donors with an Epidemiology Profile**
Contact Name:	Dr. Glenwood Trivers
Contact IC/Office:	NCI
Contact Email Address:	triversg@mail.nih.gov
Contact Phone:	301-496-2094
PI Name:	**Curtis C. Harris, M.D.**
PI Contact Information:	Email: harrisc@mail.nih.gov Phone: 301-496-2048 Fax: 301-496-0497

Contract Number:	NO2-RC-01007-74
Aims and Method:	Subject recruitment under the contract will support IRB-approved molecular epidemiology, molecular pathogenesis and translational research studies of human lung, prostate, liver, and pancreatic cancer. The lung and prostate cancer studies are ongoing. The liver study received NCI IRB approval and will start pending IRB approval at other institutions. The protocol for the pancreatic cancer study is being developed. The contract will recruit cases and hospital-based and population-based controls. All subjects will sign an informed consent and HIPAA authorization form at time of recruitment. Participation involves administration of questionnaires and collection of blood and urine from all subjects. Tumor specimens will be obtained from cases with surgery. Cases will be identified by our contractor at the participating hospitals: University of Maryland Medical Center, Baltimore Veteran Affairs Hospital, and Johns Hopkins University Clinical Center. Cases and hospital controls are undergoing routine clinical examination and treatment for a clinical condition at the participating hospitals. Our studies are not designed to influence any decision on examination or treatment of the clinical condition. Instead, we seek to identify novel markers for diagnosis, prognosis, or treatment of cancer, and the causes of the cancer health disparities between African-Americans and European-Americans. There is no direct benefit for participants, but there is the prospect of future benefits for other cancer patients. Controls are recruited for purposes of identifying environmental and genetic risk factors for cancer using the case-control design, meaning they will match cases on age, gender and race to allow an unbiased assessment of risk factor exposure.
Recruitment and Subject Care:	Subjects are recruited by trained interviewers and live in the greater Baltimore area and Eastern Shore. Cases and hospital controls will be identified through resources including centralized patient databases, lists of scheduled surgeries, and contacts with collaborating physicians and pathology departments. Population controls are selected from Motor Vehicle Administration records, contacted by mail and then by telephone. Cases and controls are consented and interviewed either at the University of Maryland or at home. We will evaluate eligibility. This is done for cases by review of medical records and by asking all prospective participants standard questions prior to enrollment. We have obtained IRB authorization for review of medical records. After eligibility has been confirmed, informed consent and authorization to obtain, use and disclose protected health information for research will be obtained. Questionnaires will be administered either the same day or at a later time point. Same applies for blood and urine collection. Subjects will not be enrolled if they are severely ill, physically/mentally not able to give informed consent, or if they reside in an institution. We have arrangements with physicians to indicate that patients should not be approached for enrollment into our studies. The risk for subjects from the participation in our studies has been deemed minimal by the IRBs, and study subjects' confidentiality will be maintained at all times. We do not provide care. However, a procedure is in place to help subjects if they would get sick or emotionally upset during the consent and interview process.

Federal-wide Assurance (FWA):	Yes
Number of Sites:	4
IRB Dates:	The contract supports two ongoing studies, one pending, and one future study. There are many IRB review dates for initial and continuous review at 4 institutions (NCI IRB, University of Maryland IRB, Baltimore VA IRB, and Johns Hopkins Univ. IRB)
All IRB Dates Entered:	Yes
Privacy Act Applies:	Yes
Comments:	All information documentation of initial IRB approval and IRB approval from annual continuous review will be provided as PDF files. IRB review and approval for studies at the University of Maryland (UMD) and the Baltimore VA Hospital is done by the UMD IRB. Applicable Federal Wide Assurance Numbers: FWA for the University of Maryland contractor: FWA00013508 FWA for Johns Hopkins University subcontractor: FWA00000287 IRB Review information: The lung cancer and prostate cancer studies have undergone IRB review and obtained approval at NCI, University of Maryland and Johns Hopkins University (as applicable) for initiation of the studies and annually with the continuous review process. Documentation of the approvals obtained at initiation and from the most recent continuous review is attached. The liver cancer study has undergone IRB review and obtained approval at the NCI. Review (see attached) and approval of this study at the University of Maryland and Johns Hopkins University is pending. The pancreatic cancer study protocol is currently being developed and we expect a protocol for review in 2010. Notification of IRB approvals for the liver and pancreatic cancer studies will be provided when obtained. Contract activities in support of the liver and pancreatic cancer studies will only begin after completed IRB approval. Supporting documents (all as PDF files) for our clinical exemption request: File descriptor (1) Protocols (3) Survey instruments (3) Initial IRB approvals (3) Current IRB approvals from continuous review (7) Statement of Privacy Act applicability for consent (1) Consent forms (19) Letters of invitation (4) Flyers (1) Instructions and letters to respondents (7) HIPAA forms (3) Medical records release authorizations (2) We will email pdf files directly to MarilynTuttleman as the total number of supporting pdf files for this application is 54. Our studies are also described at: (http://home.ccr.cancer.gov/GEMES/index.html)
Attachment 1:	Protocol (PDF - 09/15/2009)

Attachment 2:	Protocol (PDF - 09/15/2009)
Attachment 3:	Protocol (PDF - 09/15/2009)
Attachment 4:	Survey Instrument (PDF - 09/15/2009)
Attachment 5:	Survey Instrument (PDF - 09/15/2009)
Attachment 6:	Survey Instrument (PDF - 09/15/2009)
Attachment 7:	Letter of Invitation (PDF - 09/15/2009)
Attachment 8:	Letter of Invitation (PDF - 09/15/2009)
Attachment 9:	Letter of Invitation (PDF - 09/15/2009)
Attachment 10:	Letter of Invitation (PDF - 09/15/2009)