

UNIVERSITY OF KENTUCKY  
Institutional Review Board

Continuation Review  
{PROCESSTYPE}

Approval Ends  
{APPROVENDDATE}

IRB Number  
{PROTOCOLNUM}

TO: {FIRSTNAME} {LASTNAME}, {DEGREE}  
{DEPTDESC}  
{ADDRESS}  
PI phone #: {PHONE}

FROM: Chairperson/Vice Chairperson  
Institutional Review Board (IRB)

SUBJECT: Continuation Review Request for Protocol Number {PROTOCOLNUM}

DATE: {MEMODATE}

In accordance with federal regulations, the IRB conducts periodic continuing review of all currently approved projects. Your protocol entitled {PROTOCOLTITLE} is scheduled for continuation review.

If this form is not returned in a timely manner IRB approval will expire, effective at the end of your current approval period. Materials should be submitted to THE OFFICE OF RESEARCH INTEGRITY, 305 KINKEAD HALL, 0057 BY {FOLLOWUPDATE}.

If you have any questions, please contact Karen Larson at 859-257-9819 (Medical IRB #3 & #6), Gail Cadwallader at 859-257-0581 (Medical IRB #1 & #2), or Andrew Hedrick at 859-257-1639 (Nonmedical IRB #4).

SUBMIT ONE ORIGINAL AND ONE COPY OF THIS COMPLETED FORM and OF ANY ATTACHMENTS OR COVER MEMO, if applicable.

**1. STATUS OF THE RESEARCH**

Check the statement(s) that best describe(s) the current status of your research:

- No subjects have enrolled to date.
- Recruitment and/or enrollment of new subjects or review of records/specimens continue.
- Study is closed to enrollment, but subjects still receive research-related interventions (e.g., treatment, blood draws).
- Study is closed to enrollment, but subjects have completed all research-related interventions. The study remains active only for long-term follow-up.
- Study enrollment is permanently closed, subjects have completed all research-related interventions, and long-term follow-up has been completed.
- The remaining research activities are limited only to data analysis. There is access to records or specimens either directly or through codes or links to the data.
- The remaining research activities are limited only to data analysis. There is no subject/record/specimen identifying codes or links to the data; the research or research team cannot readily ascertain the subject's identity.
- Final Review. All study activities are complete. IRB approval can be inactivated. Submit a final abstract and complete all sections of this form if the information has NOT been previously reported to the IRB.

**2. PROGRESS OF RESEARCH**

- N/A Final Review
- a. In conducting continuing review on studies for which IRB approval will remain active, federal policy requires the IRB review a copy of the complete current protocol (modifications previously approved by the IRB should be incorporated into the protocol). If you are not conducting industry/pharmaceutical research, you may submit a current research description (Form B) to meet this requirement.
  - Yes  No One copy of the protocol or research description/Form B included.
  - Yes  No Changes made to the protocol or research description/Form B. If yes, submit one copy with changes underlined.
- b. If substantive changes need to be made to the original protocol, on a separate sheet briefly describe the changes and explain why they are essential.
  - Yes  No Description of substantive change(s) included.

Note: No changes in the research procedures should have occurred without previous IRB review. Approval from the IRB must be obtained before implementing any changes.

For your information, our electronic records, which began in August 1999, reflect the following total number of amendments submitted to the IRB: {MODCOUNT}

- c. Include one copy of the Investigator Brochure if it has changed and has not been previously reported to the IRB.  
 \_\_\_\_\_ Yes \_\_\_\_\_ No Changes made to the Investigator Brochure. If yes, submit one copy with changes underlined.  
 \_\_\_\_\_ N/A
- d. In conducting continuing review of research that requires FULL REVIEW (not eligible for expedited review), federal policy requires that all IRB members receive and review a protocol summary and a status report on the progress of the research. Submit TWO copies approximately one page in length of a protocol summary and a status report on the progress of the research. If your research involves extramural funding, you may use:  
 i. the most recent Progress Report Summary or project summary submitted to your funding agency to meet this requirement; OR,  
 ii. if you are conducting the study under your own IND/IDE (Investigator Sponsored), attach two copies of the most recent progress report sent to the FDA.  
 \_\_\_\_\_ Yes \_\_\_\_\_ No Two copies of the protocol summary and status report included.
- e. A new or revised grant application for this project, which has not previously been submitted to the IRB, has been submitted.  
 \_\_\_\_\_ Yes \_\_\_\_\_ No One copy of the grant proposal included.

3. **STUDY PERSONNEL**

\_\_\_\_\_ N/A Final Review

- a. Provide a list of ALL study personnel (SP). Indicate those who are to be added to the list and those who are to be removed from the list. Any study personnel currently identified in the ORI database who are not included in the submitted list of study personnel will be removed from the study. For all current and new SP, please include: Name, UK employee ID number, Rank/Degree, Responsibility in Project, and whether the person is authorized to Obtain Informed Consent. The SP template can be found on the Office of Research Integrity website at: <http://www.research.uky.edu/ori/HumanResearchForms.htm>.  
 \_\_\_\_\_ Yes \_\_\_\_\_ No Changes included in SP list.  
 \_\_\_\_\_ Yes \_\_\_\_\_ No Updated/current SP list included.  
 \_\_\_\_\_ Yes \_\_\_\_\_ No Have the new personnel completed mandatory IRB training? [see the policy on Mandatory Education for New Study Personnel and Mandatory Education Renewal (required every three years):  
[http://www.research.uky.edu/ori/human/Human\\_Research\\_Mandatory\\_Education.htm](http://www.research.uky.edu/ori/human/Human_Research_Mandatory_Education.htm)]

4. **INFORMED CONSENT**

- a. If subjects have been enrolled within the last year, and the IRB approved a consent/assent form for your study, submit two copies of the entire signed consent/assent form for the last two subjects enrolled.  
 \_\_\_\_\_ Yes \_\_\_\_\_ No Subject signed consent forms included.
- b. If applicable, submit two copies of the entire signed HIPAA Authorization forms for the same last two subjects enrolled.  
 \_\_\_\_\_ Yes \_\_\_\_\_ No Subject signed HIPAA Authorization forms for the same last two subjects enrolled included.  
 \_\_\_\_\_ N/A
- c. If the study is open to subject enrollment, submit:  
 \_\_\_\_\_ Yes \_\_\_\_\_ No Two clean copies (without the IRB Approval stamp) of the currently approved consent/assent form included.  
 \_\_\_\_\_ Yes \_\_\_\_\_ No Changes in consent/assent form requested. Two copies with the changes underlined included.
- d. Specify where the records containing the signed consent/assent forms will be located (building and room #):  
 \_\_\_\_\_
- e. If the study is open to subject enrollment and the IRB has waived the requirement to obtain a signed consent form, submit:  
 \_\_\_\_\_ Yes \_\_\_\_\_ No Two clean copies of the currently approved document used for the informed consent process (i.e. cover letter, phone script).  
 \_\_\_\_\_ Yes \_\_\_\_\_ No Changes to document used for the informed consent process requested. Two copies with the changes underlined included.

5. **SUBJECT ENROLLMENT**

- a. ORI's electronic records indicate the total # of subjects enrolled since activation of the study is: {SUBJECTCOUNTTODATE}  
 \_\_\_\_\_ The # of enrolled subjects that have not been previously reported to the IRB.  
 \_\_\_\_\_ New total # of subjects enrolled since activation of the study.
- b. Our records show the IRB approved estimate for # of subjects by completion is: {SUBJECTCOUNT}  
 Please update this estimate if necessary. \_\_\_\_\_

c. Based on the total # of subjects who have enrolled, complete the subject demographic section below. This information is available:  Yes  No If no, clarify why the information is not available:

Ethnic / Racial Category	Male		Female		Male		Female
American Indian/Alaskan Native.....	<input type="checkbox"/>		<input type="checkbox"/>	Hispanic/Latino.....	<input type="checkbox"/>		<input type="checkbox"/>
Asian.....	<input type="checkbox"/>		<input type="checkbox"/>	Native Hawaiian/ Pacific Islander.....	<input type="checkbox"/>		<input type="checkbox"/>
Black/African American.....	<input type="checkbox"/>		<input type="checkbox"/>	White.....	<input type="checkbox"/>		<input type="checkbox"/>
				Other or unknown.....	<input type="checkbox"/>		<input type="checkbox"/>

d. During the course of your research, have any prisoners been enrolled OR subjects been enrolled that became involuntarily confined/detained in a penal institution that have not been previously reported to the IRB?  
 Yes  No

Note: If yes, and you have received funding from the Department of Health and Human Services (HHS), a Certification Letter should have been submitted to the Office for Human Research Protections (OHRP); prisoners and individuals who have become involuntarily confined/detained in a penal institution cannot continue participation in the research until OHRP issues approval. If the Certification has not been submitted, contact the Office of Research Integrity (ORI) at 257-9084.

6. OFF-SITE RESEARCH

a. Is this research being conducted at an institution or facility that is not affiliated with UK or that does not fall under the UK IRB's authority.  
 No  
 Yes If yes, please provide a list of all off-site facilities at which research procedures have been or will be conducted, specifying active and non-active sites. If adding a new off-site facility, complete and submit "Form N".

7. PROJECT END DATE

a. Do you need your IRB approval to continue past the end of your current approval period of {APPROVENDDATE}?  
 Yes  No

b. The estimated project end date you provided to the IRB is {PROJECTENDDATE}. If you have a new estimated project end date, provide it here:  
 \_\_\_\_\_  
 Check here if no change.

8. DATA AND SAFETY MONITORING BOARD (DSMB) & PROBLEMS/ADVERSE EVENTS

a. Is this study monitored by a Data and Safety Monitoring Board (DSMB) or is there a Data and Safety Monitoring Plan?  
 No  
 Yes If yes, submit all documentation (i.e. summary report; meeting minutes) representing Data and Safety Monitoring activities that have not been previously submitted to the IRB?  
 Yes  No Documentation included.

Note: It is the IRB's expectation that all problems and/or adverse events requiring reporting are submitted in the appropriate time frame. Your response to this Continuation Review is considered assurance that all reportable problems/adverse events have been submitted for IRB review according to the Prompt Reporting Policy. (See the UK IRB/IBC Policy on Prompt Reporting:  
[http://www.research.uky.edu/ori/human/IRBReviewTypes.htm#UP\\_AE](http://www.research.uky.edu/ori/human/IRBReviewTypes.htm#UP_AE)

b. Were there any problems/adverse events during the last 12 months (internal and/or external; anticipated or unanticipated; serious/life-threatening or not serious/life-threatening; or related or not related)?  
 No  
 Yes If yes, submit a written summary of ALL problems/adverse events, whether anticipated or unanticipated; serious/life-threatening or not serious/life-threatening; related or not related, that occurred since the study was initiated.  
 Yes  No Summary Included.

c. Also submit the PI's assessment whether the problems/events warrant changes for the protocol, consent process, or risk/benefit ratio. The assessment should include both a qualitative and quantitative evaluation of the severity of the events and the outcome of the events.

\_\_\_\_\_ Yes \_\_\_\_\_ No Assessment included.

9. SINCE THE MOST RECENT IRB INITIAL/CONTINUATION REVIEW APPROVAL:

- a. Have there been any participant complaints regarding the research?  
\_\_\_\_\_ Yes \_\_\_\_\_ No If yes, submit a narrative summary describing the complaints.
- b. Have any subjects withdrawn from the research?  
\_\_\_\_\_ Yes \_\_\_\_\_ No If yes, submit a detailed explanation.
- c. Has any literature relevant to the research been published?  
\_\_\_\_\_ Yes \_\_\_\_\_ No If yes, submit copies of the literature.
- d. Have there been any interim findings?  
\_\_\_\_\_ Yes \_\_\_\_\_ No If yes, submit copies of the interim findings.
- e. Since the most recent IRB continuing review approval have subjects experienced any benefits?  
\_\_\_\_\_ Yes \_\_\_\_\_ No If yes, please describe below or on attached sheets.

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- f. Since the most recent IRB continuing review approval have there been any multi-site trial reports?  
\_\_\_\_\_ Yes \_\_\_\_\_ No If yes, submit copies of the reports.

10. FOOD & DRUG ADMINISTRATION (FDA)

- a. Does your protocol fall under the purview of the FDA?  
\_\_\_\_\_ Yes \_\_\_\_\_ No
- b. Has your research protocol been inspected by a FDA representative since the last IRB review?  
\_\_\_\_\_ Yes \_\_\_\_\_ No
- c. Was a FDA 483 issued?  
\_\_\_\_\_ Yes \_\_\_\_\_ No If yes, submit copies of the report(s).

11. RESEARCH FINANCIAL INTEREST DISCLOSURE STATEMENT (RFIDS)

Note: All investigators who are responsible for the design, conduct, or reporting research at the University of Kentucky are required to complete a Research Financial Interest Disclosure Statement (RFIDS).

- a. Have there been any changes to your/your investigators' personal financial situation that would require updating your Research Financial Interest Disclosure Statement (RFIDS)?  
\_\_\_\_\_ Yes \_\_\_\_\_ No If yes, complete a RFIDS (see IRB application Section 6: "Form X" for externally funded research, or "Form Y" for non-externally funded research).
- b. Have you or any of your investigators answered yes to ANY of the eight questions on that form?  
\_\_\_\_\_ Yes \_\_\_\_\_ No If yes, include two copies of the completed form, and if you have completed the Research Conflict of Interest Committee review, include a copy of the final approved management plan, contact the Office of Sponsored Projects Administration (OSPA).
- c. If the project is externally funded, has the sponsor offered any of the research team enrollment incentives or other personal benefit bonuses? (i.e. cash/check, travel reimbursements, gift checks, etc.)  
\_\_\_\_\_ Yes \_\_\_\_\_ No \_\_\_\_\_ N/A Project is Not Funded.

Note: It is University of Kentucky policy that personal benefit bonuses are not allowed. If these conditions change during the course of the study, please notify the IRB.

12. HHS PROTECTION OF HUMAN SUBJECTS ASSURANCE/CERTIFICATION/DECLARATION (310) FORM)

Note: If your study is federally funded, your funding agency may request a 310 form.

- a. Do you need the Office of Research Integrity (ORI) to complete a 310 Form for you?  
\_\_\_\_\_ Yes \_\_\_\_\_ No

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PLEASE REVIEW YOUR ADDRESS AND PHONE NUMBER PRINTED ON THE FIRST PAGE, AS WELL AS THE ITEMS BELOW; IF ANY INFORMATION IS INCORRECT, MAKE APPROPRIATE CORRECTIONS ON THIS FORM.

13. PI's Degree and Rank: {DEGREE} PI's Telephone #: {PHONE} PI's Dept: {DEPTDESC}

14. Age Level of Subject: {SUBJECTAGELOW} to {SUBJECTAGEHIGH}

15. Our records indicate that the items marked with an "X" apply to your research:

- [ ] Aborted Fetuses; [ ] Pregnant Women; [ ] Decisionally Impaired; [ ] Minors (17 yrs. or less);
- [ ] Normal Volunteers; [ ] Prisoners; [ ] Students; [ ] Surgical / Biological Specimen;
- [ ] Other Categories; [ ] Patients; [ ] Women; [ ] Decisionally Impaired (Institutionalized);
- [ ] Minors/Wards of the State; [ ] Non-English Speaking;

16. Our records indicate that you are using the Clinical Research Development & Operations Center (CR-DOC):

{YES or NO}

17. Our records indicate the following attributes apply to your research: (Mark any additional attributes with an "X", as applicable.)
- HIV / AIDS Research;  HIV Screening;  Aging Research;  Cancer Research;
  - Genetic Research;  Collection of Bio Specimens for Banking;  Emergency Use (Single Patient);
  - Psychology Dept. / SURE Committee;  Utilization of UK General Clinical Research Ctr.;
  - Multicenter Clinical Trial(exclude NIH Coop Group);  Acute Care Waiver of Informed Consent;
  - Gene Therapy;  Collection of Biological Specimens;  NIH Coop Groups (i.e. SWOG, RTOG);
  - Academic Degree / Required Research;  Drug Research;  Other Research Categories;
  - HIPAA;  HIPAA Waiver;  Alcohol Research;  Certificate of Confidentiality;
  - Clinical Research Office (UK);  Data Safety & Monitoring Board;  Deception;  Gene Transfer;
  - International Research;  Internet;  Medical Device;  Placebo Controlled Trial;
  - Recombinant DNA;  Pluripotent Stem Cell Research;  Transplants;  Vaccine Trials;
  - Waiver of Informed Consent;  Waiver of Requirement for Documentation of Informed Consent;
  - Collection of Bio Specimens for Banking(VA);

18. Our records indicate that the items marked with an "X" apply to your research:
- Approved Drug for Unapproved Use;  FDA Approved Device(s);  FDA Approved Drug for Approved Use;
  - Investigational New Device;  Investigational New Drugs;  New Drug for Cancer;
  - None of the above drug/devices;  Other Drug/Device;

19. Our records indicate the following as the funding source for your research: (Make whatever changes are necessary to correctly reflect the funding status of your research):
- Federal Agencies other than HHS/NIH;  State;  Internal Grant Program;
  - Other Institutions of Higher Education;  (HHS) Department of Health & Human Services;
  - Industry (other than Pharmaceutical Companies);  Pharmaceutical Company;
  - Private Foundation / Association;  Other Federal Agencies;  Detailed Protocol/Grant Application;
  - General Clinic Research Center;  (NIH) National Institutes of Health;
  - (CDC) Center For Disease Control;  (SAMHSA) Administration;
  - (HRSA) Health Resources and Services Administration;  Veteran's Affairs (VA);
  - National Science Foundation;

UKRF Grant/Contract # \_\_\_\_\_

Funding source and/or cooperating organization(s): \_\_\_\_\_  
(e.g., National Cancer Institute, Ford Foundation, Eli Lilly & Company, South Western Oncology Group, Bureau of Prisons, U.S. Department of Justice, etc.)

20. Select and use appropriate statement below:

**For Extramurally Sponsored Studies or FDA Regulated Studies**

\_\_\_\_\_ I have reviewed all the investigational data from this study, including a compilation of all internal and external adverse event/unanticipated problems along with information from the sponsor including, if applicable, updated investigator brochures and data and safety monitoring board reports and conclude that the human subject risk/benefit relationship is not altered and that it is not necessary to modify the protocol or the informed consent process.

OR

\_\_\_\_\_ I have reviewed all the investigational data from this study, including a compilation of all internal and externally generated adverse event/unanticipated problems along with information from the sponsor including, if applicable, updated investigator brochures and data and safety monitoring board reports and conclude that the risk/benefit relationship has been altered. We have previously or are in the process of submitting requests, with this report, for modification of the research protocol and informed consent process.

**43a. For Studies Without Extramural Funding**

\_\_\_\_\_ I have reviewed all the investigational data from this study, including a compilation of all internal and external adverse event/unanticipated problems and conclude that the human subject risk/benefit relationship is not altered and that it is not necessary to modify the protocol or the informed consent process.

OR

\_\_\_\_\_ I have reviewed all the investigational data from this study, including a compilation of all internal and externally generated adverse event/unanticipated problems conclude that the risk/benefit relationship has been altered. We have previously or are in the process of submitting requests, with this report, for modification of the research protocol and informed consent process.

Principal Investigator Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Please retain a copy of this completed application in your study records.