TO: 
FROM: Chairperson/Vice Chairperson
Institutional Review Board (IRB)
SUBJECT: Continuation Review Request for Protocol Number x
DATE: 

In accordance with federal regulations, the IRB conducts periodic continuing review of all currently approved projects. Your protocol entitled xxxxx 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, 315 KINKEAD HALL, 0057 BY XXX

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 describes 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 enrollment is permanently closed; subjects have completed all research-related interventions; and the study remains active only for long-term follow-up of subjects. *
___ 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 researcher 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.

* Possibility that review will move from Full to Expedited

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. If yes, submit one copy of the protocol or research description/Form B included.

___ Yes ___ No
___ Yes ___ No

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

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/human/HumanResearchForms.htm  
      ___ Yes  ___ No  Changes included in SP list.  
      ___ Yes  ___ No  Updated/current SP list included.  
      ___ Yes  ___ No  Have the new personnel completed the 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]  

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 forms 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. 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. CONFIDENTIALITY/SECURITY  
   Review your Research description (Form B) and update the Confidentiality portion, if necessary, to describe measures for  
   security of electronic and physical data research records (e.g. informed consent document(s), HIPAA Authorization forms,  
   sensitive or private data).

6. SUBJECT ENROLLMENT  

   a. ORI's electronic records indicate the total # of subjects enrolled or records/specimens reviewed since activation  
      of the study is:  
      SUBJECTCOUNTTOTDATE  
      ____  The # of enrolled subjects or records/specimens reviewed that have not been previously reported to the IRB.  
      ____  New total # of subjects enrolled or records/specimens reviewed since activation of the study.

   b. Our records show the IRB approved estimate for # of subjects or records/specimens reviewed  
      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:

<table>
<thead>
<tr>
<th>Ethnic / Racial Category</th>
<th>Male</th>
<th>Female</th>
<th>Ethnic / Racial Category</th>
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<th>Female</th>
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</thead>
<tbody>
<tr>
<td>American Indian/Alaskan Native</td>
<td>____</td>
<td>____</td>
<td>Hispanic/Latino</td>
<td>____</td>
<td>____</td>
</tr>
<tr>
<td>Asian</td>
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<td>____</td>
<td>Native Hawaiian</td>
<td>____</td>
<td>____</td>
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<tr>
<td>Black/African American</td>
<td>____</td>
<td>____</td>
<td>Pacific Islander</td>
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<tr>
<td>American</td>
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<td>____</td>
<td>White</td>
<td>____</td>
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<tr>
<td>Other or unknown</td>
<td>____</td>
<td>____</td>
<td></td>
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</tr>
</tbody>
</table>

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 has 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.

7. 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, 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".

8. PROJECT END DATE
   a. Do you need your IRB approval to continue past the end of your current approval period of xxxx?
      ___ Yes ___ No
   b. The estimated project end date you provided to the IRB is xxxxxxx. If you have a new estimated project end date, provide it here:
      _________________________ Check here if no change.

9. DATA SAFETY MONITORING BOARD (DSMB)
   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 reported to the IRB. Please check applicable statement:
      ___ Documentation included.
      ___ Documentation has been previously reported to the IRB.

10. UNANTICIPATED PROBLEMS INVOLVING RISK TO SUBJECTS OR OTHERS/ADVERSE EVENTS
    Please Note: It is the IRB’s expectation that all unanticipated problems involving risk to subjects or others or related deaths requiring prompt reporting are submitted in the appropriate time frame [See Policy: http://www.research.uky.edu/ori/SOPs_Policies/2-AE_policy.pdf]. Your response to this Continuation Review is considered assurance that all prompt reportable problems/adverse events have been submitted for IRB review.
    Submit a written summary of both unanticipated problems* and available information regarding adverse events since the last initial or continuation review. The amount of detail provided in such a summary will vary depending on the type of research being conducted; in many cases, such a summary could be a brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and investigator’s brochure (if applicable). The summary must include the PI’s assessment whether the problems/adverse events warrant changes to the protocol, consent process, or risk/benefit ratio.

*For multisite studies, the written summary should describe external events determined to be unanticipated problems involving risk to subjects or others.

11. 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 new and relevant literature been published since the last IRB review, especially literature relating to risks associated with the research?
Yes No If yes, submit copies of the literature as well as a brief summary of the literature including, if pertinent, the impact of the findings on the protection of human subjects.

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

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.

12. FDA
   a. Does your protocol fall under the purview of the Food & Drug Administration (FDA)?
      Yes No

   b. Has your research protocol been inspected by a FDA representative since the last IRB review?
      Yes No

   b. Was a FDA 483 issued?
      Yes No If yes, submit copies of the report(s).

13. 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. If you do not have a 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.

14. 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

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.

15. PI's Degree and Rank: xx  PI's Telephone #: (859)xxx-xxxx  PI's Dept: xxx

16. Age Level of Subject: xxx

17. 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;

18. Our records indicate that you are using the Clinical Research Development & Operations Center (CR-DOC): [YES or NO]

19. Our records indicate the following attributes apply to your research: (Mark any additional attributes with an "X", as applicable.)
20. 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;

21. 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 #_________________

22. SELECT THE APPROPRIATE STATEMENT BELOW:

a. For Externally Funded/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.

b. For Studies Without External 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 record.