

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 for Nonmedical full and expedited reviews at 859-257-1639.

ATTACHMENTS AND # OF COPIES REQUIRED

- _____ 1. TWO copies of this completed form.
- _____ 2. TWO copies of any attachments or cover memorandum, if applicable.
- _____ 3. 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.
_____ a) If applicable, submit two copies of the entire signed HIPAA Authorization forms for the same last two subjects enrolled.
- _____ 4. If open to enrollment, submit TWO clean copies of the currently approved consent form (WITHOUT the "IRB Approval" stamp) OR if open to enrollment, and the IRB has waived the requirement to obtain a signed consent form, submit the approved copy of the document used for the informed consent process (i.e. cover letter, phone script).
[NOTE: If approved, the form(s) will be returned to you with an accompanying approval stamp: Only informed consent/assent documents with a valid "IRB Approval" stamp can be used to enroll subjects.]
_____ CHANGES REQUESTED IN CONSENT/ASSENT DOCUMENT SUBMITTED?
**If you are making changes to the consent document(s), include two copies with the changes underlined, and provide an explanation of how the changes differ from the currently approved consent form.
- _____ 5. If you have submitted a new or revised grant application for this project that has not previously been submitted to the IRB, submit one copy of the grant proposal.
- _____ 6. 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.

Please attach ONE copy of the most current protocol (or research description/"Form B", if applicable), and include a copy of the Investigator Brochure (if applicable) if it has changed since the last review.

_____ Changes made to protocol/research description ("Form B")?
IF YES, INCLUDE ONE COPY WITH THE CHANGES UNDERLINED.
- _____ 7. 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:
a) use the most recent Progress Report Summary of project summary submitted to your funding agency to meet this requirement: OR,
b) if this is a VA Research and Development Committee approved study, you may submit the Project Data Sheet with the abstract attachment to meet this requirement; OR,
c) 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.
- _____ 8. In you are closing the study, summarize the results of your study and state that this is a final abstract.

COMPLETE THE FOLLOWING ITEMS (# 9-34)

9. Do you need the Office of Research Integrity (ORI) to complete an HHS Protection of Human Subjects Assurance/Certification/Declaration (310 Form) for you?
(If your study is federally funded, your funding agency may request a 310 Form.)
10. Check all that apply:
- a) The study is permanently closed to enrollment of new subjects.
 All subjects have completed all research-related interventions.
 The study remains active for long-term follow-up of subjects.
- b) The only remaining activity for this study is data analysis.
[NOTE: As long as data analysis is being conducted, your protocol should remain under IRB approval unless certain circumstances are met. For details, see the UK ORI/IRB Study Closure SOP:
http://www.research.uky.edu/ori/human/SOPs_&_Policies.htm#4
Update #11 if necessary.]
- c) IRB approval can be inactivated (all study activities are complete).
11. a) Do you need your IRB approval to continue past the end of your current approval period {APPROVENDDATE}?
- 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.
12. a) ORI's electronic records indicate the total # of subjects enrolled since activation of the study is: {SUBJECTCOUNTTODATE}.
- b) The # of enrolled subjects that have not been previously reported to the IRB.
 New total # of subjects enrolled since activation of the study.
- c) Is your study closed to enrollment of new subjects?
- d) Our records show the IRB approved estimate for # of subjects by completion is: {SUBJECTCOUNT}
 Please update this estimate if necessary.
13. 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?

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 can not continue participation in the research until OHRP issues approval. If the Certification has not been submitted, contact the Office of Research Integrity (ORI) at 257-3038.

14. Subject Demographic Information
Please complete this section based on subjects who have enrolled in the study.

Check here if the information is not available, and clarify why:

Ethnic / Racial Category	Male Female	Male Female	
American Indian/Alaskan Native.....	____ ____	Hispanic/Latino.....	____ ____
Asian.....	____ ____	Native Hawaiian/ Pacific Islander.....	____ ____
Black/African American.....	____ ____	White.....	____ ____
		Other or unknown.....	____ ____

15. Is the research being conducted at any site other than UK Campus, UKMC, VAMC, or Markey Cancer Center?
If YES, please provide a detailed list of all off-site facilities, specifying active and nonactive sites, at which research procedures have been or will be initiated. If adding a new off-site facility, complete and submit "Form N".

16. a) Is the study open at the VA Medical Center?

b) Is the study currently enrolling human subjects from the VA?

c) Are there any VA human subjects in follow-up?

[Note: If "Yes" to a, b, or c, your study is considered a "VA study". If this is not a VA study, please answer "N/A" for any VA questions that follow.]

For items 17 - 19, report events which have not been described on any prior renewal/continuation review applications. If you have no events to report, please answer questions 17 - 19 with "no".

17. Have any subjects withdrawn from the research?
**If yes, attach a detailed explanation.
 If this is a VA study, provide the cumulative number of subjects withdrawn since inception of the project.

18. Have there been any complaints about the research?
**If yes, attach a detailed explanation.

19. Please answer the following:

a) Has any recent relevant literature developed during the course of the research?

b) Have any interim findings developed during the course of the research?

If yes to either question, discuss their implications for subject participation on additional sheets.

20. Since the last IRB Continuation Review, have subjects experienced any benefits? If yes, please describe below or on attached sheets:

21. Provide a complete list of study personnel (SP). This list should include all SP who are currently listed (highlight new SP and indicate who should be removed from the list). **Please note:** 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. Attach two copies of the current list of SP. The SP template can be found on the Office of Research Integrity website at: <http://www.research.uky.edu/ori/human/HumanResearchForms.htm>

CHANGES MADE TO SP LIST?

UPDATED SP LIST ENCLOSED?

22. 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]

23. 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.

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}

24. Unless the requirement for documentation was waived by the IRB, a copy of the approved informed consent/assent form should have been signed by each of the subjects in the study.

Has this requirement been met?

25. Specify where the records containing the signed consent/assent forms are/will be located (bldg. & room #):

26. Since the last IRB Continuation Review, have there been any relevant multi-site trial reports?
**If YES, and the reports have not already been submitted to the IRB, please attach.

27. Is this study monitored by a Data Safety and Monitoring Board (DSMB) or is there a Data Safety and Monitoring Plan?
**If no, proceed to Question 29.

28. Attach 2 copies of any summary Data Safety Monitoring report that has been issued during the last 12 months.

Yes, attached

No reports issued

29. 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)?
**If yes, complete #30.

[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)]

30. Provide a written summary of all problems/adverse events that occurred since the study was initiated (whether anticipated or unanticipated; serious/life-threatening or not serious/life-threatening; or, related or not related) and the PI assessment whether the problems/events warrant changes for the protocol, consent process, or risk/benefit ratio. The summary should include both a qualitative and quantitative assessment of the severity of the events and the outcome of the events. (Attach summary)
31. _____ Does your protocol fall under the purview of the Food & Drug Administration (FDA)?
**If yes, please respond to items 32 and 33.
32. _____ Has your research protocol been audited by a FDA representative since the last IRB review?
33. _____ If YES, was a FDA 483 issued?
**If yes, please include a copy with this form.
34. a) 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)**.
_____ Have there been any changes to your/your investigators' personal financial situation that would require updating your **Research Financial Interest Disclosure Statement (RFIDS)**?

**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? If yes, include two copies of the completed form, **and** if you have completed the Research Conflict of Interest Committee review, 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).
35. _____ If the project is funded by extramural funding, has the sponsor offered any of the research team enrollment incentives or other personal benefit bonuses? (these benefits could take the form of cash/check, travel reimbursements, gift checks, etc.)

_____ Not Sponsored

Please 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.

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REVIEW THE ITEMS BELOW.
PLEASE MAKE APPROPRIATE CORRECTIONS ON THIS FORM.

36. PI's Social Security #: {SOCIAL SECURITY NUMBER} Degree and Rank: {DEGREE}
PI's Telephone #: {PHONE #} PI's Dept: {DEPARTMENT}
37. Age Level of Subject: {SUBJECT AGE (YOUNGEST)} to {SUBJECT AGE (OLDEST)}
38. a) 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;
- b) If this is a VA study, provide the number of subjects enrolled from each category of subject marked in 38a (e.g., Name of subject category: #). _____
39. Our records indicate that you are using the Clinical Research Development & Operations Center (CR-DOC):
{YES or NO}
40. 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);

41. 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;
42. 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.)

43. 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.