UNIVERSITY OF KENTUCKY
Institutional Review Board

Continuation Review	Approval Ends	IRB Number
Expedited Review	x	x

TO: x
x

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

SUBJECT: Continuation Review Request for Protocol Number x

DATE: x

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. Unless you are importing an application into E-IRB, in which case, this report form and applicable attachments should be combined into a single PDF and uploaded to the Additional Information section of your E-IRB application, this form and all attachments should be submitted to IRBSUBMISSION@UKY.EDU in a single Adobe PDF document BY XXX. For E-IRB imports, see the video tutorial "How to Import a Full or Expedited Protocol" for additional details.

If you have questions, please contact the Office of Research Integrity at (859) 257-9428 or via email at IRBSUBMISSION@UKY.EDU.

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. *
PLEASE NOTE: OHRP interprets "long-term follow-up" to include:
Research interactions that involve no more than minimal risk to subjects (e.g., quality of life surveys); and
Collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol.

OHRP interpretation of "long-term follow-up" does not include: Research interventions that would not have been performed for clinical purposes, even if the research interventions involve no more than minimal risk.

___ 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

Note: For Applicable Clinical Trials remember to ensure compliance with registration and result reporting on Clinicaltrials.gov.

___ 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. Attach a summary of all modifications approved by the IRB since initial review or the last continuation review, which may impact subject safety or welfare.
_____ Yes _____ No Summary of modification(s) included.

c. If substantive changes need to be made to the most recently approved protocol/research description, on a separate page 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}

d. 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

e. 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 a summary approximately one page in length 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 the most recent progress report sent to the FDA.
___ Yes ___ No The protocol summary and status report included.

f. A new or revised grant application for this project, which has not previously been submitted to the IRB, has been submitted.
___ Yes ___ No 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 the entire signed consent/assent forms for the last two subjects enrolled.
___ Yes ___ No Subject signed consent forms included.

b. If applicable, submit 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 A clean copy (without the IRB Approval stamp) of the currently approved consent/assent form included.
___ Yes ___ No Changes in consent/assent form requested. Consent form 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 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. Consent document 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: {SUBJECTCOUNTTODATE}
_____ 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:

_____

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

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, 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, revise applicable items in "Form A - General Information Sheet", "Form B - Research Description", and all other documents (e.g. consent forms, brochures, advertisements) which will list the off-site facility. Submit all revised documents with this report.

_____

_____

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

_____
_____

12. Food and Drug Administration (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. DISCLOSURE OF FINANCIAL INTEREST (DFI)

Do you, any of your investigators, or key personnel have a significant financial interest requiring disclosure (per the UK administrative regulation: http://www.uky.edu/regs/files/ar/ar7-2.pdf)
___ YES ___ NO
AND the interest(s) relate(s) to this project?
___ YES ___ NO
(to make this determination, see OSPA [http://www.research.uky.edu/ospa/coi.html] and/or download a sample form to view the questions required to make this determination)

If YES to both questions above, do you, any of your investigators, or key personnel need to update (or submit) an online financial disclosure?
[instructions:
http://www.research.uky.edu/ospa/info/docs/INSTRUCTIONS%20FOR%20COMPLETING%20THE%20FINANCIAL%20DISCLOSURE%20FORM.pdf]
___ YES
___ NO UPDATE REQUIRED (e.g., disclosure is already up-to-date)

If YES, please identify who has submitted an updated (or new) online financial disclosure:
Name:_____ Name:_____
Name:_____ Name:_____
Name:_____ Name:_____

Note: The IRB cannot issue final IRB approval without reviewing the final approved management plan, if one has been deemed necessary.

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 CCTS Clinical Services Core: *{YES or NO}*

19. 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);

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;

OSPA Account #_____
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.)

Note, when research is submitted to, supported by, or conducted in cooperation with certain federal agencies, specific requirements apply. For guidance on which agencies (and to help ensure you are in compliance), see ORI's web page for Federal Agency Specific Requirements: http://www.research.uky.edu/ori/IRB-Survival-Handbook.html#FedAgency

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_____(not required if importing application in E-IRB)

Date:_____

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

REQUIRED for CHANGES INCORPORATED into an APPLICATION IMPORTED into E-IRB

For each proposed change, describe the currently approved procedures, forms, etc. and then summarize the proposed change, addition, etc. Include a justification for the change(s). Add additional sheets if necessary.

Example:

Currently Approved: study staff as listed on SP List for former IRB #07-0261-F2L

Proposed Revision: add Jane Doe, MD, as co-investigator, Dr. Doe has completed human subject protections training, Dr. Doe is a new faculty member who will be working with subjects on this protocol and she is authorized to obtain consent.

Currently Approved:

Proposed Revision:

Currently Approved:

Proposed Revision:

Currently Approved:

Proposed Revision:

Currently Approved:

Proposed Revision: