



University of Kansas Medical Center

Human Subjects Committee

Answering HSC Provisos

What are provisos?

The Human Subjects Committee's (HSC) review of new submissions, recertifications, and requests for amendment may result in four possible outcomes: approved, deferred, tabled, or disapproved. The HSC Staff notifies the investigator of the outcome by means of a letter shortly after the review. If the outcome of the review was either deferred or tabled, the letter will include a list of questions/concerns, also known as *provisos*, which must be addressed and resubmitted to the HSC for review. Investigators have 45 days from the review date to submit a *response to provisos*. If a response is not submitted within this time period, the file will be administratively terminated.

How should I format my response?

When formulating a response to provisos, follow the instructions below to ensure the most efficient and timely review:

- **Compose a cover letter numerating each proviso and response separately.** It is important that your cover letter is clear, concise, and complete. Label each response with the corresponding proviso number so that it is clear how you are replying to the issue raised by the HSC.
- **Include a highlighted version of the revised consent form with the proviso numbers in the margin next to the corresponding highlighted revision (if applicable).** If your provisos include revisions to the consent form, you must supply a copy of the newly revised consent form with all changes highlighted. In order to clearly show that each requested revision has been made, write the number of the proviso (ie., HSC #1, HSC #2, etc.) in the margin next to the highlighted section.
- **Attach any supporting documentation requested by the Committee.** If you have any questions about documents that the Committee has requested, please contact the HSC Office at 8-1240 or at humansubjects@kumc.edu.
- **ONLY COMPLETE RESPONSES WILL BE REVIEWED.** Do NOT submit partial responses. If for any reason you are not able to answer a proviso right away, hold on to your response and wait until you are able to submit a complete response.

How do I submit my response?

Submit **TWO (2)** copies of your response to the HSC Office located in G006 Sudler, M.S. 1032. Responses that require Committee review (see *How will my response be reviewed* below for details) are subject to the submission deadlines dates listed at: http://www2.kumc.edu/researchcompliance/forms/HSC_MeetingDates_2005.pdf

Please Do Not Use Staples on Any Submission Items

How will my response be reviewed?

The proviso letter you receive following HSC review will indicate whether your response to provisos will require Chairman or Committee review. Provisos issued following a Full Committee review (i.e., initial submission, a request for amendment, or a previous response to provisos) that require substantive (may affect the risk/benefit ratio) revisions must be re-reviewed by the Committee. Provisos on all other Full Committee and Expedited reviews may be reviewed by the Chairman.

Responses that are going for Committee review are subject to submission deadlines (see *How do I submit my response* above) and will be discussed by the Committee at the following HSC meeting. Response that are eligible for Chair review will be screened for completeness by the HSC Staff within five (5) days of submission. Once the initial screen is complete, the response will be forwarded to the Chairman for review. The timeliness of the Chairman's review is dependent upon workload and availability.

Notification of the outcome of the review will be sent to the Principal Investigator and/or any associated cooperative divisions (i.e., Clinical Trials Office, General Clinical Research Center, etc.). If you have not received a notification of the outcome of your review within eight (8) business days, you may contact the HSC Office (8-1240 or humansubjects@kumc.edu) to inquire about the status of your response.

What if I have a question about a proviso?

If you have any questions regarding your provisos, no matter if they are substantive or administrative issues, please contact the HSC Office at 8-1240 or humansubjects@kumc.edu.

What if I do not respond to the provisos for my new project within 45 days, my file is terminated, and then I decide that I want to try to start up the project again?

In order to re-open a project that was submitted, reviewed, provisos issued, and then administratively terminated due to a failure to respond to those provisos within 45 days you must submit a brand new application for the project INCLUDING the revisions that were requested following the previous review. Also, you must include a cover letter explaining that this project had been reviewed before (include the original HSC # assigned to the file) and you would now like to re-open the project for review.

What if I decide not to answer the provisos and I would like to terminate/withdraw the project from HSC review?

- **Withdrawing initial review submission with pending provisos**– If you have submitted a project for initial review, received provisos, and now do not want to answer the provisos or continue with the project, submit a letter to the HSC explaining that you do not wish to continue with the project and will not be answering the provisos.
- **Withdrawing a request for amendment with pending provisos** – If you have submitted a request for amendment, received provisos, now do not wish to respond to the proviso, and would like to withdraw the amendment completely,

submit a letter to the HSC explaining that you would like to withdraw the amendment.

- **Terminating a research project with pending provisos** – If your project has already received initial approval and you have submitted an action (recertification, request for amendment, response to provisos, etc.) which received provisos but you now wish to terminate the entire project, submit a Summary Progress Report (SPR) detailing that you would like to discontinue your project.

What if within the 45 days after the provisos have been issued there are revisions that need to be made to the project? Can I submit a combined response to provisos and amendment request together?

Yes, you may submit a response to provisos and request for amendment together as long as the revisions are highlighted and clearly identified in the margins of the consent form and/or protocol. In other words, the revisions due to provisos and those due to the amendment must be clearly differentiated so that the reviewers can easily distinguish between them.

There are provisos regarding my consent form revisions, is my old consent form still valid until these issues are resolved?

Yes. Until the new version of the consent form is approved, you must continue to use the previously approved consent form and operate under the procedures as defined within that consent. The procedural changes initiating the need for the consent form revision may not be implemented until the amendment and revised consent form is approved.