



University of Kansas Medical Center

Human Subjects Committee

Duration of HSC Approval

Why does my study have an expiration date?

Federal regulations require that research studies involving human subjects, which were initially approved by the *full committee* or through the *expedited* review process, must be reviewed at least once a year. The HSC has the discretion to review a study more than once a year if the Committee determines that there are risks associated with the study such that it is in the subjects' best interests that the study be monitored more often. The expiration date that is issued is the date by which the Primary Investigator must submit a Summary Progress Report (SPR) as a request to continue conducting research activities on the project and comply with the continuing review provision of federal regulations. This process is commonly referred to as *recertification*.

Studies that are initially approved as *exempt* do not require annual review and, as such, are not issued an expiration date at the time of approval. The exemption class criteria are listed on the *Application for Exemption Classification*, which can be found at: http://www2.kumc.edu/researchcompliance/forms/HSC_Application_for_Exemption_Classes.pdf

How is the expiration date calculated?

Initial submissions and recertifications that have been reviewed and approved by the full committee are approved for one year from the last HSC meeting at which the submission was reviewed. Studies may end up going to several HSC meetings before they are approved, but the expiration date is calculated using the last convened committee meeting at which the submission was reviewed.

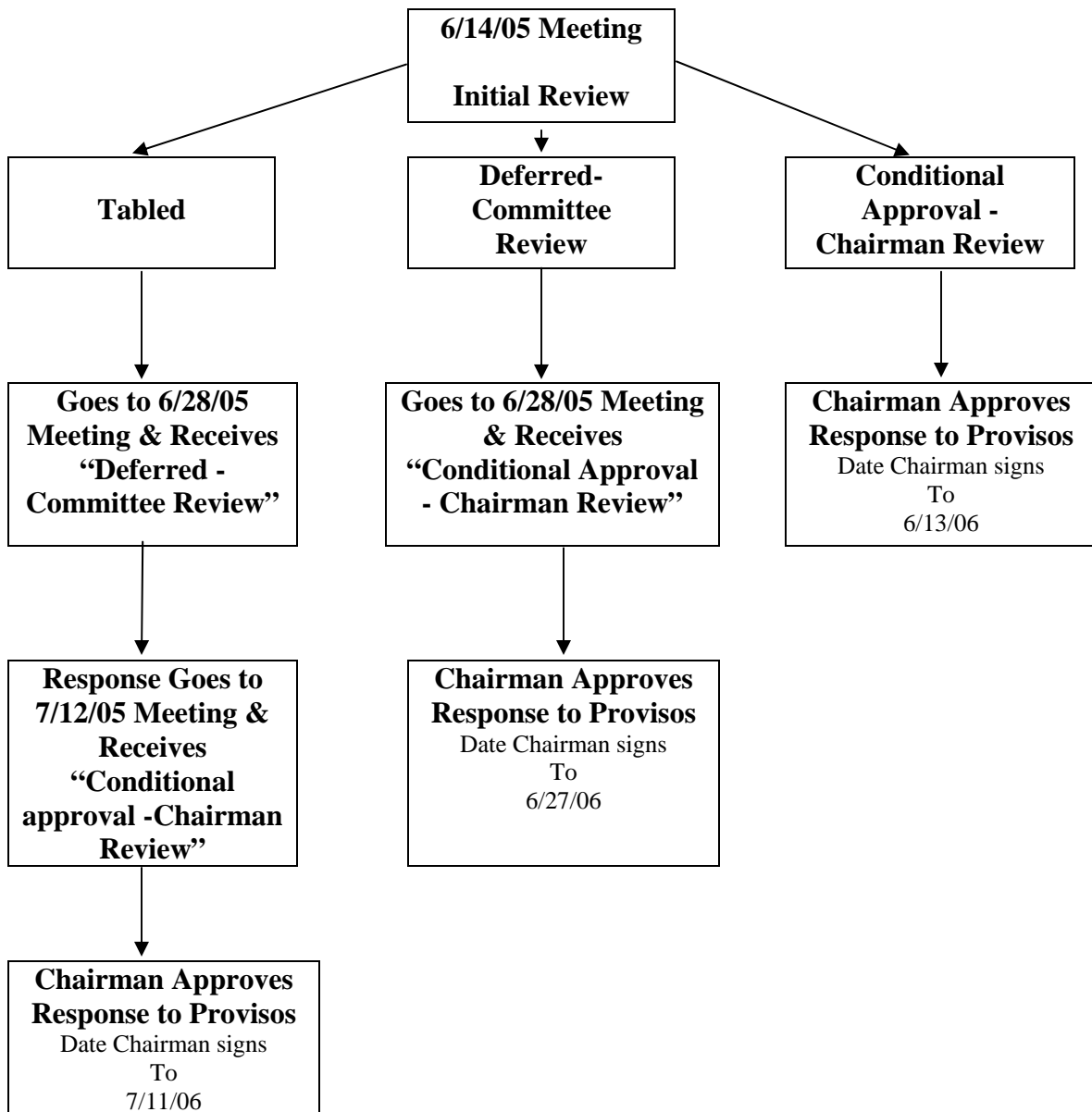
Expedited submissions, however, are not reviewed by the full committee and therefore do not go to an HSC meeting. Since these submissions are not reviewed by a convened committee, the expiration date is calculated as 364 days from the date of approval. Listed below are three scenarios and a flow chart showing how expiration dates are calculated:

- **Scenario 1 (Full Committee Recertification)**: An investigator submits an SPR to the HSC Office in order to recertify his/her study. The study was initially reviewed and approved by the full committee, therefore the recertification must also go back to the full committee for review. The submission was handed in to the HSC Office on 6/3/05, which was the deadline for the 6/14/05 HSC meeting. The study is reviewed by the HSC at the convened meeting and the recertification was approved. This study will now be approved from **6/14/05** (the date that the Committee approved the recertification) to **6/13/06** (one year following the HSC meeting at which the submission was reviewed).
- **Scenario 2 (Full Committee Initial Review)**: An investigator submits a new study to the HSC Office for initial review. The risk/benefit ratio of the study is great

enough that it requires full committee review. The submission was handed in on 6/3/05 for the 6/14/05 HSC meeting. The HSC determines that there are clarifications and modifications (i.e., provisos) that the investigator must address. The outcome of the vote is “Conditional Approval – Additional Chair Review Required.”

The investigator submits a response to proviso on 6/21/05 which is logged in by the HSC Staff and screened for completeness and clarity. The response is then reviewed and approved by the Chairman and a representative of HIPAA on 6/22/05. This study would be approved from **6/22/05** (the date of approval) to **6/13/06** (one year from the HSC meeting at which the study was reviewed).

If the outcome had been “Deferred – Additional Committee Review Required,” then the study would have to go back to a second HSC meeting. If it is approved or the Committee determines that any further provisos can be reviewed by the Chairman, then this second meeting becomes the meeting by which the expiration date is determined. See the flow chart below:



- **Scenario 3 (Expedited Initial Review):** An investigator submits a new study to the HSC Office for review on 6/3/05. The study contains minimal risk and meets the criteria for expedited review (<http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>). The study is screened by the HSC Staff for administrative completeness and then forwarded to the Chairman, the HIPAA representative, the Conflict of Interest Committee representative, and the Institutional Research Safety Committee representative for review. All parties review the studies and a list of provisos is formulated and sent to the investigator on 6/9/05.
The investigator submits a response to provisos on 6/14/05. The response is screened by the HSC Staff and then submitted to the appropriate parties for review. All parties approve the study on 6/16/05. This study would be approved from **6/16/05** (the day it was approved) to **6/15/06** (364 days after approval since the study was never reviewed by the full committee at a convened HSC meeting).

When I submit a request for amendment, does my expiration date get renewed since the study is being reviewed again?

No. Expiration dates are originally set following initial review and are extended only through recertification. The reason for this is that there is information requested on the SPR that is necessary for recertification that is not submitted with a request for amendment (updated number of subjects enrolled, adverse event reports since the last continuing review, publications, etc.) If your amendment request involves consent form revisions, once approved your new consent form will be dated from the amendment approval date to the previously determined expiration date.

What if I'm not going to get my SPR in to the HSC Office in time to recertify my project by the expiration date? Can the HSC grant an extension?

No. The Primary Investigator MUST recertify the study BEFORE the set expiration date. Federal regulations are very clear in stating that all non-exempt research must be reviewed at least annually.

If an investigator does not recertify a study in time, it will expire and be administratively terminated on the expiration date and all research activities must stop.