1) How do I know the expiration date of IRB Approval for my study? When your study is initially approved the letter you receive will specify the approval period and the expiration date, which is the last day of that period. It is important that you note that date and plan ahead so that the Continuing Review report (HRP-212 arrives in the IRB office six weeks prior to the expiration date.

2) How does IRB approval lapse? When IRB continuing review of research does not occur by the last day of the approval period, expiration is automatic. For example: a study approved from July 15, 2014 through July 14, 2015 will automatically expire at midnight on July 14, 2014. Every study is approved for a specified period of time, whether it poses minimal risk to subjects (expedited review), or whether it poses greater than minimal risk (full review).

3) Who is responsible for submitting the Continuing Review report on time? The Principal Investigator is responsible for everything that occurs during a study. He or she may delegate appropriate workload to research staff (such as filing the Continuing Review report), but the responsibility for maintaining IRB approval throughout the life of the study remains with the PI. This is why it is so important for a PI to periodically meet with study staff and know what is going on during the study, even though he or she may not be involved in every daily task required to conduct the study successfully.

4) What happens when my study lapses in IRB Approval? Under federal regulations all research activities must stop. This includes all aspects of a study including: recruitment, advertisement, screening, new enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information. Advertisements currently running in the media must be pulled. All study activity must cease unless it falls into the activities described in Question 5.

5) What if I need to continue to treat a subject on a clinical trial before the Continuing Review can be reviewed and approved by the IRB? Continuation of research activities without prior IRB review and approval is a violation of federal regulations.

However, in some studies it would put subjects at risk of harm by stopping some research procedures (such as study medications, for example). The key to activity in this category is identifying study procedures that provide direct benefit to subjects. When you believe
that current subjects are at risk of harm if research procedures stop, you must
immediately notify the IRB office by filing a Reportable New Information form (HRP-
214) that documents the following:
- A written list of subjects who will be harmed.
- Describe any research procedures that need to continue.
- Describe why these procedures need to continue, including how they provide direct
  benefit to subjects and thus prevent harm.

The IRB will determine whether an over-riding safety concern or ethical issue exists such
that it is in the best interest of individual subjects to continue study procedures during the
lapse in IRB Approval.

6) **What can I do so that IRB approval does not expire?** Consider how best to track study
expiration dates in your office so that you can meet the six week deadline. Remember
that the deadline applies to when the report should be in the IRB office. So, for example,
electronically or on a hard copy calendar you could note the date that is **eight weeks** prior
to your study expiration date, which will provide plenty of time to prepare the report in
your office and make sure it is received by the IRB **six weeks prior to the expiration date**
of your study.

7) **What are the consequences of IRB approval lapsing?** Conducting a study after IRB
approval expires is just as serious as initiating your research without IRB approval. The
Office of Human Research Protections considers expiration of IRB approval to constitute
serious noncompliance whether it occurs once in a single study, more than once in a
study, or once in more than one study conducted by the same Principal Investigator. The
latter two events could also constitute continuing noncompliance. Serious and/or
continuing noncompliance must be reported to Federal Authorities. Additionally, if the
continuing review application is not received by the date requested in your initial
approval letter (six weeks prior to expiration), you will be restricted from submitting new
human research applications to the IRB until the study has been renewed.

8) **Where can I find more information about continuing review?** The form is available
also explained in Advocate’s Investigator Manual (HRP-103)
[http://www.advocatehealth.com/forms2](http://www.advocatehealth.com/forms2) (HRP-103 is the first item on the list and can be
accessed as a pdf document).

9) **Who can I call with questions?** Call or email the IRB office: 630-929-6151;
jasmine.taylor2@advocatehealth.com.