



## Notification of Change in Practice

The approval date on consent documents must be updated to the date of the scheduled continuation reviews (SCR) approval. The practice affects all studies in Legacy and eResearch. Practice is effective in the Legacy (paper-application) system with the SCR approved on or after 10/3/06 and in the eResearch system on or after 7/21/06.

### **Past Practice:**

At time of SCR approval:

- The expiration date of the study on the consent document(s) was updated.
- The consent approval date was updated if and only if the consent document included approved revisions other than the expiration date.
  - If there were no revisions to the consent document its previous approval date was maintained.

### **New Practice:**

At time of SCR approval:

- The expiration date of the study on the consent document(s) must be updated.
- The consent approval date must be updated.
  - This will occur even if there are no revisions to the document.

### **Actions Required by Study Teams:**

*No immediate actions are required by this announcement. When (and if) you submit an SCR:*

**Studies in the Legacy (paper-based) system:** When you receive an approval notice for an SCR, update the consent document such that:

- the expiration date on the consent matches the new expiration date on the approval notice
- the 'consent approval date' matches the SCR approval date on the approval notice

**Studies in the eResearch system:** When you receive an approval notice for an SCR, the IRBMED updates the consent document(s) as required and places the approved consent in eResearch under the Documents tab in the Approved Study Workspace.

### **Regulatory Rationale:**

HHS regulations at 45 CFR 46.111 set forth the criteria that must be satisfied in order for the IRB to approve research. These criteria include, among other things, determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards for human subjects. The IRB must ensure that these criteria are satisfied at the time of both initial and continuing review. The IRB must ensure the following:

- The currently approved or proposed consent document is still accurate and complete;
- Any significant new findings that may relate to the subject's willingness to continue participation are provided to the subject in accordance with HHS regulations at 45 CFR 46.116(b)(5).

Updating of the approval date on the consent document reflects these considerations as well as reflecting the revision of the change in expiration date. This practice follows guidance of the HHS Office of Human Research Protections and the practices of other major research institutions.