

April 10, 2015

Jefferson IRB Announcement - Subject Initial Requirement on Consent Form Eliminated

As of today, April 10, 2015, the Office of Human Research has eliminated the requirement for subjects to initial and date each page of the OHR-8 consent form. The OHR-8 template will be revised to remove this section from the footer and will be updated on the IRB website shortly.

For currently active studies, you do not need to submit an amendment to remove this section from your consent form. As of today, you may simply ignore the section and the requirement. If sponsors query you about this, you may use this email as formal documentation from the Office of Human Research. This announcement will also be posted on the IRB website. At the time of continuing review, if your consent form needs re-stamping, please revise to remove the subject initial/date section from the footer.

Keep in mind that the amendment policy (IC 702) does require that when the IRB has determined that subjects should be re-consented with a revised consent form, they initial & date revised pages and sign the signature page. (Once initial & date lines have been removed from the OHR-8 template, subjects can initial & date anywhere in the margin of revised pages.)