Recent Consent Changes Overview – 7/1/15

Within the last six or so months we have made multiple changes to our consent form template which has resulted in various questions from researchers about how to and when it is appropriate to make the requested changes. An up-to-date list of frequently asked questions is posted on our website for reference. The changes are listed below.

November 2014 – Change in hospital name – PI is responsible

April 2015 – Simplification of the compensation for injury language – PI is responsible

July 2015 – Change to IRB approval stamp located on last page of consent forms – RPO staff are responsible

When and How

New protocol approvals will not be released until all three of these items have been addressed. RPO staff will let you know if something needs to be done.

Continuing approval of ongoing protocols that are more than minimal risk and still consenting will not be released by RPO staff until all three items have been addressed. RPO staff will let you know if something needs to be done.

Amendments that otherwise require consent language changes will not be released by RPO staff until all three items have been addressed. RPO staff will let you know if something needs to be done.

PLEASE DO NOT SUBMIT AN AMENDMENT FOR ANY OF THESE ITEMS UNLESS YOU ARE REQUIRED TO CHANGE THE CONSENT FORM FOR ANOTHER REASON AS THIS WILL BURDEN THE PROCESS AND RESULT IN DELAYS.

THERE IS NO ABSOLUTE DEADLINE TO INCLUDE THESE ITEMS. IF THEY HAVE NOT BEEN INCLUDED BY THE NEXT CONTINUING REVIEW, IT WILL BE REQUESTED AT THAT TIME.