1) I have a patient coming in tomorrow. If I submit my revised consent form to you via email can't you just approve it?

No, any change to a consent document requires an amendment form. To address the urgency of relaying this new information about the name change, we have developed the Consent Update Form. This form, which is located on our consent forms page, is to be provided to the subject until you have had the opportunity to submit an amendment or continuing review. Please do not submit an amendment with the name change only, make sure that you have other necessary changes.

2) Why can't I submit an amendment with the name and compensation for injury language change only?

The IRB has approximately 1200 ongoing protocols of which 80% include the main hospital or associated campuses, if everyone were to submit for this purpose alone, all other review activities would grind to a halt. If you have an amendment that affects the consent form, then go ahead and include the injury language and name change as well, otherwise please hold off on submitting.

3) If the injury language and name change is done at the time of continuing review, is an amendment form also needed?

In this case we have made an exception to the rule. If the injury language and name change is done at continuing review you do not need to submit an amendment form as well. However, to ensure our records match, please highlight the changes and update the footer date on the consent form so IRB staff is clear that only these two items changed within the consent document at time of continuing review.

4) When we update the HIPAA Authorization, do we use the new streamlined version of the HIPAA form or just update the name on the current version?

The new streamlined version of the HIPAA Authorization is only for new protocols. We do not want two completely different versions of HIPAA Authorizations within the same study. So when you are updating your consent form with the name change you should update the HIPAA Authorization with only the name change.

5) We have subjects who no longer come to clinic for follow-up visits, but we remain in contact with them to obtain their current status. They signed their consent form a long time ago. Do we need to share the Consent Form Update with those individuals?

It is not necessary to share the document with subjects who are no longer coming in for study visits. Certainly feel free to inform them verbally the next time you are conducting a phone follow-up.
6) (new 5/18/15) I have already provided the hospital name change to my subjects. Do I really have to now go back to them with this injury language change?

The answer is it depends. The injury language was revised solely to simplify for subjects. The coverage in the event of an injury has not changed. If the subject is still undergoing protocol treatment or any protocol-related procedures that are more than minimal risk (e.g., CT scans, bone marrow), you must provide them with the injury language. There is still the potential for a protocol-related event in these subjects, therefore we must make sure they understand the compensation for injury.

If the subject has finished treatment and all protocol-related procedures that are more than minimal risk, it is not necessary to provide them the new injury language.

7) (new 5/18/15) My existing consent does not have the injury language at all. Do I have to add this new language now?

No, if your originally approved consent form does not have the injury language it was determined not to be necessary. Therefore, you do not need to add it now.

8) (new 7/1/15) I have been submitting a clean copy of the consent for the new stamp each year. Are you saying we don’t need to do that each year now?

For one full year the RPO staff will be working with researchers to affix the new IRB stamp of approval. The continuing review form has been revised to ask a specific question about which form you are currently using. This question will help you to determine whether you need to submit a clean copy for the new IRB stamp. Also, you can always contact the office for assistance in making this determination.