Frequently Asked Questions Regarding the Hospital Name Change

Updated 12/5/14

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 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 name change as well, otherwise please hold off on submitting.

3) If the name change is done at the time of continuing review, is an amendment form also needed? FAQ updated 12/5/14

In this case we have made an exception to the rule, if the name change is done at continuing review you do not need to submit an amendment form as well. However, to ensure that our records match, please highlight the name change and update the footer date on the consent form so that both you and we are clear in the future that only the name changed within the consent at time of continuing review.

4) When we update the HIPAA Authorization, do we use the new streamlined version of the HIPAA 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 as well.

5) We have subjects who no longer come to clinic for follow-up visits, but we do contact 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 longer coming in for study visits. Certainly feel free to inform them verbally the next time you are conducting a phone follow-up.