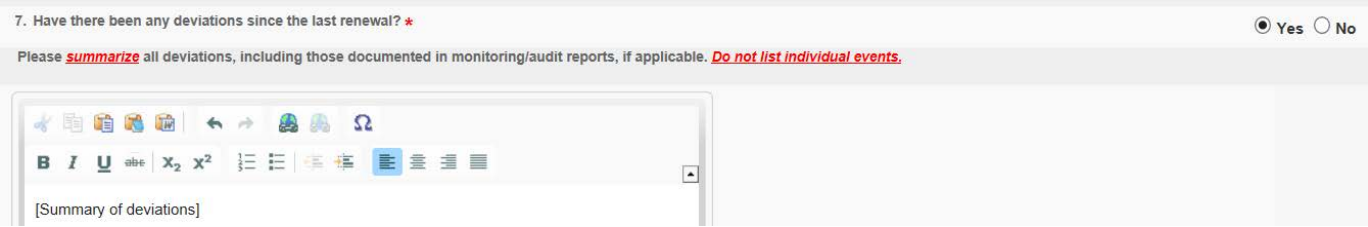
IRB Changes to Reporting of Deviations at Continuing Review

What does this change apply to?

Currently, protocol deviations qualifying as New Safety Information (NSI) are submitted via an NSI submission in IRBIS, and those that do not qualify as NSI are summarized at the time of continuing review.

This change applies to reporting of deviations that do not qualify as NSI (i.e., "all other deviations")

Current Progress Report question shown below:



What are the changes?

A summary of all other deviations that do not constitute NSI will **no longer be required to be provided at the time of continuing review**.

Will the IRB still review study deviations?

Yes. Study deviations will be reviewed as part of post-approval monitoring by the IRB and/or the Clinical Trials Quality Assurance (CTQA) program. If the PI is employed by one of the UNC HC Network Entities (i.e., UNC-Rex, High Point Regional or Johnston), study deviations may be reviewed by the Office of Research Support & Compliance (ORSC). The IRB may also request your deviations records during its review of NSI. With this change, you will need to provide study deviation records at the request of the IRB.

How will I provide the deviation to the IRB for review?

At the request of the IRB, you may provide the deviation log to the IRB outside of IRBIS. The procedure for providing the deviation log will be outlined at the time of the request.

Why are the changes being made?

This new process is a way to meet regulatory requirements, focus resources on review of deviations involving increased risks to subjects, and reduce burden on IRB reviewers and investigators.

Do I need to do anything?

Aside from no longer providing deviation summaries at continuing review, you should be tracking study deviations as before. If you do not already have a deviation log for the study, we highly recommend you begin using the deviation log template provided here: https://research.unc.edu/files/2018/06/Protocol-Deviation-Tracking-Log.docx

If you choose to use a different form, be sure that the one you use includes all the same elements as found in the template.

It is even more important now to familiarize yourself with SOP 1401, as failure to promptly report NSI could be considered serious or continuing noncompliance.

When does this go into effect?

Use of a deviation log should begin immediately, if you have not already done so. The target date for the changes in IRBIS is **Tuesday, July 3, 2018**. Requests for deviation logs may be requested any time following the change.

What if the sponsor requires that I submit all deviations to the IRB?

Refer the Sponsor to SOP 1401 for a description of deviations that are reportable to the IRB. If they still have questions, they may contact the UNC-CH IRB directly at (919) 966-3113 or irb_questions@unc.edu.