Reliance Agreement Updates 2019 – Summary of Changes

- All the forms and guidance documents related to reliance have been updated to align versions and make minor clarifications.

- We have developed a new quick reference document geared toward assisting external sites with the process for submitting to the Penn IRB via the study point of contact. We hope this new document is helpful for communicating and organizing multiple sites. Its use is not required.

- Major changes only apply to the Continuing Review forms. The process is still the same, however the content requirements have been updated to align with the newer standard continuing review.
  - To re-cap the process; the Penn IRB has developed a system where each site (including the Penn site) can fill out the “Relying Site Supplement” for continuing review and provide them back to the point of contact who compiles and submits the continuing review to the Penn IRB. That person can then utilize the combined information within those site-specific forms to fill out the “Single/Central” IRB continuing review form and draft a master progress report. All the site-specific forms and the Central form are then submitted to the IRB through HSERA along with any other needed supporting documents (Progress reports, protocol, ICFs, drug/device information etc...)

- The most significant change is regarding reporting of Deviations. Please be sure to review our published guidance regarding deviations and continuing review available here- https://irb.upenn.edu/continuing-review

- These new Continuing Review forms will not be required until you submit continuing review in 2020. We hope that is enough time to review your multi – site management plans and make any necessary adjustments.

- The Guidance document titled “Post Approval Submission Guidance” has been updated significantly to include more detail about what the IRB requires at the time of continuing review. Review of this guidance is important to understanding the process for maintaining approval and compliance of external sites throughout the duration of the study.

- The Penn IRB recognizes that not all multi- site management plans will support the specific process that the IRB has created for multi-site continuing review. It is generally acceptable to submit the required information to the IRB via a different format as long as all required information is present for all sites. The IRB staff is willing to work with your team to obtain clear and organized submissions in a way that does not create unnecessary burden to meet the criteria for approval.