Q2 eIRB Changes

**Re-Open Process for Closed Studies:**
Study teams wishing to re-open a closed study will now have a specific process for doing so and will no longer need to do this through a standard continuing review

- When the study team views a closed study in eIRB, they will now see an option to “Create a New Re-Open”. This replaces the option to “Create a New Continuing Review”, which has been removed.
- Re-opens being submitted in order to review existing data can be approved more quickly than before and can be more clearly identified in the eIRB.
- Re-opens being submitted in order to collect new data will walk the study team through the creation of a new study.

**Purpose of the Changes:**

- Separating re-opens from standard continuing reviews will allow for better management of continuing review expiration dates.
- Majority of re-opens will require less work on the part of both study teams and IRB, improving overall efficiency.

**CRSO Study Start-up Approval to be Routed Through eIRB Beginning July 1:**
CRSO approval indicates the CRSO has received a fund code associated with the study, and, if the study has “Billing Risk”, a charge assignment grid has been approved. When these approval conditions have been met, a line in the study’s History in the eIRB will appear, similar to the functionality used by the Office of Research Administration (ORA) to indicate a fully executed contract agreement. If a study progresses to the point at which it has been approved by the IRB, and, if applicable, has an ORA approved contract agreement, but has not yet received CRSO approval, an automated e-mail will be sent to the study team with instructions on resolving the remaining issues. Study teams will not receive an approval letter within eIRB until all institutional requirements have been fulfilled. As a reminder, study teams can, at any time, look up the fund code and grid statuses of their studies in the Subject Billing Registry. Please contact CRSO.Help@notes.duke.edu with any questions.