

## 2019 Summary of Changes Site Signature and Delegation of Responsibilities (DOR) Log Version 2.0 Q3 2019

- Aligned and reformatted the log instructions and PI attestations on page 1
- Eliminated the Start Date columns from the PI signature. It is understood that the start of the log is the PI signature on page 1.
- PI end of study declaration statement was moved from the last page to page 1 of the log
- An optional Sponsor comments section was added to page 1
- Study Tasks
  - Task codes were reorganized and categorized to align with qualifications
  - IP was changed to SI in accordance with usual TransCelerate language
  - Assess safety notifications, unblind/unmask, discuss medical content of informed consent were added as new tasks in response to member company feedback
  - Tasks codes receive/access safety notification, screen/recruit study subjects were removed
  - The task code determine eligibility criteria (inclusion/exclusion) replaces confirm eligibility criteria
  - The task 'Ship biological samples' was separated from the collect/process of biological samples
  - For further clarification, Perform basic assessments was changed to perform study activities
  - 'other' task codes were added for both medically qualified trained licensed staff and the trained/qualified staff sections of the task list
- Within the Log:
  - Modifications to the PI initials and date column to require PI to contemporaneously date the initials
  - Removal of Start (dd/mm/yyyy) and corresponding instructional text to eliminate confusion that may result from repetitive dates
  - Removal of the following language at the end of page 2:
  - Refer the PI to the guidance document regarding change of PI ; text eliminated from the log
- Comments
  - Added a comments box to each page of the log with a reminder that the site staff are to initial/date any comments
  - Removed the 'check box' to be marked if there are no comments
- Miscellaneous
  - Additions of R2 to the ICH GCP E6 title
  - Provided more space when completing the task portion of the form
  - Added further explanation that the end of tasks date is completed when staff exit during the study

## Site Signature and Delegation of Responsibilities (DOR) Guidance Document

- Re-organized layout to flow better instruction and ease

- Update language around ICH E6 R2
- Adjusted the instructions to reflect the updated DOR log