**FOR A CLINICAL TRIAL:**

Complete the AURA-IRB CR submission form, including:

Provide update on study progress in the current approval period

Provide status of all enrolled subjects, e.g. whether the subjects are on study, completed study, are in follow up, etc.

If the study is closed to enrollment but research activities are ongoing, specify what research activities are ongoing

If the study is open to enrollment and/or subjects are still on study, provide literature searches

Summarize internal and external safety events and/or deviations

If Phase III, upload current monitoring report from DSMB

Upload monitoring report from other monitoring Committee(s)

Upload CR form(s) for any relying site(s)

Review personnel list to determine it is current; verify that all personnel listed in AURA personnel list are in compliance with BSD Training policy\*

If amendments are in process, ensure any changes and information in the amendment are reflected in the continuing review form\*\*

**FOR OTHER RESEARCH:**

Complete the AURA-IRB CR submission form, including:

Provide update on study progress in the current approval period

If there is subject interaction, provide status of all enrolled subjects, e.g. whether the subjects are on study, completed study, are in follow up, etc.

For data collection studies, clarify if new data continues to be collected

As applicable, literature searches are provided

As applicable, deviations and safety events are described or summarized

As applicable, upload monitoring report from monitoring Committee(s)

Upload CR form(s) for any relying site(s)

Review personnel list to determine it is current; verify that all personnel listed in AURA personnel list are in compliance with BSD Training policy \*

If amendments are in process, ensure any changes and information in the amendment are reflected in the continuing review form\*\*

\* If personnel are no longer in compliance, please ensure either training is updated or applicable person(s) are removed via amendment. Submit personnel change amendment concurrently with CR form.

\*\*For example, if the amendment is requesting to re-open the study, the CR form should NOT indicate that the study is permanently closed. Or, if the amendment indicates that current subjects will be asked to re-consent, the CR form should NOT indicate that all subjects are deceased.