**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.