

What is the purpose of the self-assessment?

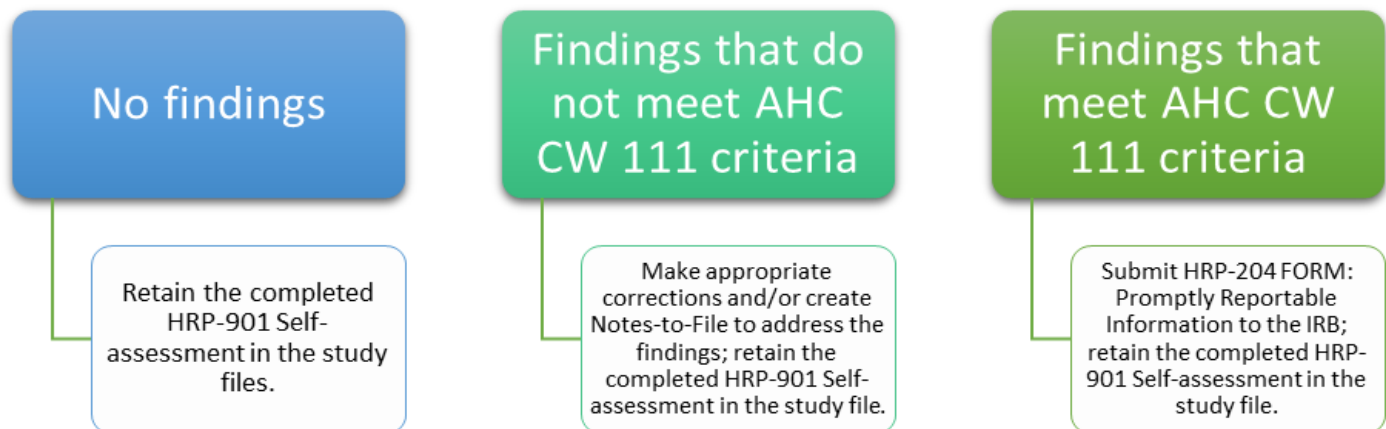
Self-assessments are recognized by regulatory and accreditation agencies as an effective method to strengthen the quality, efficiency, and effectiveness of Human Research Protection Programs (HRPPs). Results aid in identifying strengths and weaknesses of our HRPP.

How are studies selected for self-assessment?

Studies are selected randomly from the current list of active projects. Six studies are selected each month with five receiving notices to complete the self-assessment and one held as an alternate. A study will not be selected for self-assessment more than once in a 12-month period.

How do I report results of the self-assessment?

Findings of self-assessments are reported to the IRB in accordance with CW AHC 111POLICY: Prompt Reporting Requirements in Research.



Do I need to complete the self-assessment for the entire study?

Yes. The self-assessment is intended to assist the research team with maintaining regulatory compliance. The entire study record should be reviewed; however, not all sections of the self-assessment checklist will apply to all studies.

Do I need to complete the self-assessment if the study has not been activated, is closed to enrollment, or if I plan to close the study?

Yes. All studies that have IRB oversight are subject to selection for and completion of self-assessment. There may be parts of the assessment that cannot be completed based on the study status. You should complete as much of the assessment as possible and document why some sections cannot be completed.

Do I need to complete the self-assessment if the study relies on an external IRB?

Yes. Studies that rely upon external IRBs are still subject to AdventHealth policies and procedures related to the conduct of research.