

# **Routine Audit Report**

## **Study Summary:**

This would be a brief synopsis of the study as it exists at the time of the review.

**The overall rating for this review was .....**

**Excellent:** No deficiencies noted.

**Good:** No compliance issues or key findings. Few other/common findings to correct.

**Fair:** Compliance issues or Key findings that need corrective action.

**Poor:** Compliance issues, key finding and numerous protocol deviations.

## **Compliance Issues:**

Requires the Executive IRB Committee to address and notify Principal Investigator in a debriefing letter with a required time line for corrective action

## **Key Findings:**

This area would be used to list important key issues regarding consents, documentation, and protocol deviations.

The Executive IRB Committee would address these findings in the debriefing letter to the principal investigator, as well.

## **Other Findings:**

These finding will be listed in a “bullet type” fashion. This would facilitate a quick glance at the common/other findings that are contained in the body of the routine review report that the committee members read prior to the scheduled IRB Executive Committee Meeting.

## **Local Campus IRB File Review:**

This would include the local IRB’s record of review. This would guarantee quality improvement across the board.

