• **Report indicates no findings**
  - No follow-up with the IRB is required when there are no findings

• **Report indicates findings that the Principal Investigator (PI) after review and assessment of all necessary information can assure will not affect the following:**
  - Participant safety (note: this is not necessarily a negative outcome, it is whether the finding may have impacted subject safety)
  - Participant’s rights or willingness to participate
  - Data integrity (i.e. participants data cannot be used in the final analysis due to the finding or will somehow impact how their data is used)
  - Research conduct that might warrant a revision, required report of deviation to the IRB, submission of a reportable event or any other action that would meet “real time” reporting to the IRB
    - **Does this report require follow up with the IRB?** If the PI can assure all the above, which should be documented in the regulatory file so that this can be reference for future monitoring/auditing, no follow-up with the IRB is required in real time
      - **NOTE:** These types of findings that do not warrant real time reporting to the IRB can be summarized at the time of continuing review, either via the progress report or can be referenced when drafting the monitoring summary that accompanies the continuing review request (if applicable), but this is not required
    - If the PI cannot assure all the above or requires guidance from the IRB related to whether a finding is real time reportable, the PI (or an appropriate designated member of their study team) should either report the finding(s) to the IRB formally or request IRB assistance to determine which finding(s) may warrant real time reporting for consideration (NOTE: The IRB website guidance section on reportable events is a useful resource to review definition of reportable event.)

• **Report indicates findings that the PI after review and assessment of all necessary information feels may have impacted any of the following:**
  - Participant safety (note: this is not necessarily a negative outcome, it is whether the finding may have impacted subject safety)
  - Participant’s rights or willingness to participate
  - Data integrity (i.e. participants data cannot be used in the final analysis due to the finding or will somehow impact how their data is used)
  - Research conduct that might warrant a revision, required report of deviation to the IRB, submission of a reportable event or any other action that would meet “real time” reporting to the IRB
    - **Does this report require follow up with the IRB?** Real time reporting requirements will apply (see SOP 404 section for real time reporting timelines and requirements )and the reporting timeline begins from the date that the PI has determined that any of the above parameters may be affected by the finding(s) (NOTE: this date should be documented for tracking purposes to assure that real time reporting requirements were met)

• **Report indicates findings, but the findings include which the PI after review and assessment of all necessary information can explain/address in the response to the internal monitoring/auditing entity and the explanation will negate the findings impacting any of the following criteria:**
  - Participant safety (note: this is not necessarily a negative outcome, it is whether the finding may have impacted subject safety)
Guidance for engaging the IRB after receipt of an internal monitoring/auditing report:

- Participant’s rights or willingness to participate
- Data integrity (i.e. participants data cannot be used in the final analysis due to the finding or will somehow impact how their data is used)
- Research conduct that might warrant a revision, required report of deviation to the IRB, submission of a reportable event or any other action that would meet “real time” reporting to the IRB

  **Does this report require follow up with the IRB?** If the PI can assure all the above, which should be documented in the regulatory file so that this can be reference for future monitoring/auditing, no follow-up with the IRB is required in real time
  - NOTE: These types of findings that do not warrant real time reporting to the IRB can be summarized at the time of continuing review, either via the progress report or can be referenced when drafting the monitoring summary that accompanies the continuing review request (if applicable), but this is not required

- Report indicates findings, which initially are not determined by the PI to affect the following, but after compiling the responses to the internal monitoring/auditing findings, there is a potential impact on any of the below:
  - Participant safety (note: this is not necessarily a negative outcome, it is whether the finding may have impacted subject safety)
  - Participant’s rights or willingness to participate
  - Data integrity (i.e. participants data cannot be used in the final analysis due to the finding or will somehow impact how their data is used)
  - Research conduct that might warrant a revision, required report of deviation to the IRB, submission of a reportable event or any other action that would meet “real time” reporting to the IRB

  **Does this report require follow up with the IRB?**
  Real time reporting requirements will apply (see SOP 404 section for real time reporting timelines and requirements) and the reporting timeline begins from the date that the PI has determined that any of the above parameters may be affected by the finding(s) (NOTE: this date should be documented for tracking purposes to assure that real time reporting requirements were met)