This document has been developed to assist study teams with completing an appropriate Monitoring Summary for the IRB at the time of continuing review. Below is the language from the related section of the continuing review form with additional explanation. The later sections provide more specific guidance and examples.

IV. Monitoring Report Summary (Greater than Minimal Risk Biomedical Research Only)

Please note: This section is not required for any biomedical research continuing reviews that are eligible for expedited review. If your study is minimal risk, has not enrolled any subjects to date, or you are closed to enrollment and had no active subjects during the year being reported, please skip this section.

As part of the continuing approval request process, the Principal Investigator and their team are required to conduct a self-assessment of monitoring/auditing activity.

(The completion of an appropriate monitoring summary will likely require the participation of several study team members including the PI. Especially for investigator initiated studies. It is not recommended for one person to attempt to complete it from beginning to end.)

To meet this requirement; please create and attach a summary report that includes the following information from the past year:

- The methods used to develop the summary (PICA only? Site visit reports? Combination?)
- If site monitor/auditing visits are included in your monitoring plan, please describe the planned frequency and account for any deviations from the existing plan
- An overall determination about study conduct derived from the monitor/auditing activities
  (There are 2 basic types of determinations:
   1. The monitor/auditing activities were performed/ reviewed and no issues were noted therefore no changes are planned for the coming year.
   2. The monitor/auditing activities were performed/ reviewed and the following issues were noted: In response to these issues, the following modifications are planned once the continuing review has been approved:
      *Please note that based on the structure of your study’s monitoring plan other determinations may be possible)
- For examples and additional guidance on drafting a monitoring summary please see the IRB website

Please see clarifications below to determine what steps to take in drafting your monitoring summary based on your study’s approved monitoring/auditing plan:

A. For studies that either: 1) do not undergo external monitoring/auditing by a Sponsor, Funding Agency, Office of Clinical Research, Abramson Cancer Center Department of Compliance and Monitoring, or other external monitor/audit; or 2) have not had a monitoring/auditing visit within the past approval year
   - Please complete the Principal Investigator Compliance Assessment (PICA) and then create a separate summary document that highlights the findings of that assessment activity.
     (The PICA is required for studies with this type of monitoring plan in order to ensure that the monitoring being performed by the PI and study team is in alignment with monitoring that is typically performed by an industry sponsor monitor or other monitoring entity)
   - Please do not upload the Principal Investigator Compliance Assessment form to the continuing review, but maintain a copy for your records.
     (If a PICA is uploaded, the submission will be returned.)

B. For studies have had at least one monitoring/auditing visit within the past approval year from a Sponsor, Funding Agency, Office of Clinical Research, Abramson
Cancer Center Department of Compliance and Monitoring, or other external
monitor:
• Please provide a separate summary of the monitor/audit(s) findings and potential impact on the
conduct of the research and/or protections for the human participants. (If the monitor’s review of the study does not address all the elements of the PICA, a PICA should be completed for the missing elements only and referenced in the summary.)
• Please do not upload any monitor/auditing reports, but maintain a copy for your records. (The IRB does not want monitoring reports or letters uploaded because they typically do not include an overall determination. The IRB is asking the study team to review all their monitoring reports for the year and develop a determination about whether changes are needed in the new approval year or confirmation that everything is running as planned.)

Regarding the Principal Investigator Compliance Assessment (PICA):
Although there are conditions under which a given study would not require the completion of a PICA checklist, all study staff that support greater than minimal risk biomedical research are expected to be familiar with the PICA in order to assess whether a PICA is needed to supplement an external monitor/auditing process. If you are unsure whether a PICA is required for your study in any given year, please contact the compliance office within OCR for additional guidance in making that assessment prior to submitting your continuing review.

Is there a designated area for the Monitoring Summary?
No. The IRB will accept a monitoring summary within any site controlled document being provided with the continuing review. The only requirement is to clearly distinguish your monitoring summary from the other information being provided.

• When including the summary within the progress report, please clearly designate a section for “Monitoring Summary”
• If a cover letter is preferred, please clearly designate a section within your cover letter for “Monitoring Summary”
• You may also submit a “Monitoring Summary” as a separate word or PDF document.

Examples of Monitoring Summaries
*Note: These are fictional examples to convey to submitters how a monitoring summary should sound.

Type A: “The monitoring plan for this study includes site visits by the sponsor. However the first site visit has not occurred but is planned in alignment with the 10th subject completing their first round of infusion. A PICA was completed to supplement and we have found no issues.”

Type A: “We completed the PICA and found that a modification is needed to better align our document versions. A modification will be submitted after the continuing review is complete. No other issues were found as a result of completing the PICA.”

Type B: “The site was visited by the CRO on Feb.16, April 30, and September 9. A monitoring visit is planned for December 15. No issues were noted and no changes to the study conduct are necessary.”

Type B: “The monitoring plan from the sponsor includes quarterly site visits by the CRO. Our first monitoring visit was scheduled for May 12 however it was rescheduled for August 1st. During the visit it was noted that one subject was consented with an outdated version of the consent form. A deviation will be submitted to the IRB. The study team will be retrained on checking version dates prior to beginning the consent process.” (If this deviation had already been reported and acknowledged by the IRB, it should not be included in the summary.)