1. Background:
   1. Short description of background on experimental procedure(s)
   2. Short description of aims
2. Briefly describe the report.
3. If the report involves non-compliance[[1]](#footnote-1), check the project history to see whether reports of similar non-compliance have been submitted.
4. Determine whether the report involves non-compliance, serious non-compliance[[2]](#footnote-2) or continuing non-compliance[[3]](#footnote-3).
   1. If the report involves non-compliance, determine whether the corrective and preventive action plan (CAPA) is adequate.
   2. If the CAPA Is not adequate, recommend specific actions to improve the CAPA.
5. Determine whether the report involves an unanticipated problem involving risk to subjects or others (UPIRTSO)[[4]](#footnote-4)
   1. If the report involves a UPIRTSO, determine whether any revisions need to be made to the consent document to inform subjects; or to the protocol to minimize risks.
   2. If revisions are required, determine whether enrollment should be temporarily halted pending the revision(s).
6. Determine whether the criteria for approval are still met.
   1. If the criteria for approval are no longer met, describe concerns.
7. Determine whether recruitment should be halted pending revisions.
8. Determine whether enrollment or the study should be suspended.
9. Determine whether approval of the study should be terminated.

**Sample Review**

This study involves an investigational drug for \_\_\_\_\_\_\_\_.

Primary aim is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Secondary aims are \_\_\_\_\_

This report involves \_\_\_\_\_\_\_\_\_\_\_\_\_.

(If non-compliance) There are \_\_\_\_ reports of similar non-compliance in the project history.

This information meets/does not meet the definition of non-compliance/serious non-compliance/continuing non-compliance/UPIRTSO.

(If non-compliance) The CAPA is/is not adequate. The CAPA should be revised to include\_\_\_\_\_\_.

(If non-compliance or UPIRTSO) I recommend the following revisions to the protocol/consent document \_\_\_\_.; or I do not recommend any revisions to the protocol/consent document.

Criteria for approval continue to be/are no longer met,

(If not met) \_\_\_\_\_\_is no longer met because \_\_\_\_\_\_\_\_\_.

Recruitment should/should not be halted pending revisions.

Enrollment in the study should/should not be suspended.

Approval of the study should/should not be terminated.

1. [↑](#footnote-ref-1)
2. 1 Non-Compliance: Failure to comply with the requirements of an applicable law, regulation, or institutional policy pertaining to the protection of human subjects, and/or with the requirements or determinations of an IRB. For Department of Defense (DOD) research, non-Compliance includes failure of a person, group, or institution to act in accordance with Department of Defense (DOD) Instruction 3216.02 and its references, or applicable requirement.

   2 Serious Non-Compliance: Noncompliance that adversely affects the rights or welfare of participants. For Department of Defense (DOD) research, Serious Non-Compliance includes failure of a person, group, or institution to act in accordance with Department of Defense (DOD) Instruction 3216.02 and its references such that the failure could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject’s willingness to participate in research; or damage or compromise the scientific integrity of research data. [↑](#footnote-ref-2)
3. Continuing Non-Compliance: A pattern of noncompliance that indicates an inability or unwillingness to comply with the requirements of an applicable law, regulation, or institutional policy pertaining to the protection of human subjects and/or with the requirements or determinations of an IRB. (In other words, do you believe that the current CAPA will be effective in preventing future, similar non-compliance?) [↑](#footnote-ref-3)
4. Unanticipated Problem Involving Risks to Subjects or Others: An incident, experience, or outcome that meets all of the following criteria:

   1. Unexpected (in terms of nature, severity or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

   2. Related or possibly related to participation in the research (*possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

   3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred. [↑](#footnote-ref-4)