IRB Tip Sheet: Practical Review of Continuing Reviews

An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in § 46.109(f).

From the OHRP Continuing Review Guidance:

- **When conducting continuing review (CR), the IRB should start with the working presumption that the research, as previously approved, does satisfy all criteria for approval.**
- The IRB should focus on whether there is any **new information** provided by the investigator, or otherwise available to the IRB, that would alter the IRB's prior determinations, particularly with respect to the IRB's prior evaluation of the potential benefits or risks to the subjects.
- The IRB should assess whether there is any **new information** that would necessitate revision of the protocol and/or the informed consent document.
- If the IRB determines that the protocol no longer meets criteria for approval, the IRB must require changes that would result in research satisfying these criteria, defer taking action, or disapprove the research.

Completing your review before the IRB Meeting:

1. *Review the CR PROTECT Smart Form*
   - **Enrollment and Study Status:**
     - Total enrollment and enrollment since the last review
     - Status of the study as expressed in research milestones
     - Has enrollment been appropriate for meeting the study's goals?
   - **Optional Checkboxes** (Most of the information you need to complete your review will be in this section and will fall under the categories OHRP recommends focusing on during a CR):
     - **Risk assessment and monitoring:** unexpected problems or adverse events, data safety monitoring reports (DSMB), new information regarding risks or changes in potential benefits (outside publications or information from other sites or trials)
     - **Adequacy of the process for obtaining informed consent:** frequency of short form use in various languages
     - **Investigator and institutional issues:** subject complaints, new information on changes in resources
     - **Research progress:** interim findings, subject withdrawals, publications, multicenter trial reports
   - **Noncompliance:** If noncompliance occurs, a summary of the events since the last review will be provided.
     - **Major Deviations** and events of noncompliance that do not qualify as a deviation are reported as RNIs in PROTECT. A final determination regarding these events is made by OHSRP Leadership or the Research Compliance Review Committee (RCRC). At that time, they also review any corrective actions to make sure that they are sufficient. These determinations cannot be revisited, and the RNIs do not generally need to be viewed by the IRB at CR.
     - **Minor Deviations** are only reported at the time of CR and are reviewed by the IRB in aggregate with the major deviations by looking for patterns that would suggest **continuing noncompliance**. The IRB cannot make the final determination themselves but can instruct the research team to submit an RNI describing the concerning events. The RNI will then be reviewed by OHSRP Leadership to determine if RCRC review is required.
     - **Definition of Continuing Noncompliance per Policy 802:** *"A pattern of recurring non-compliance that either has resulted, or, if continued, may result in harm to subjects or otherwise materially compromise the rights, welfare and/or safety of subjects, affect the scientific integrity of the study or validity of the results. The pattern may comprise repetition of the same non-compliant action(s), or different non-compliant events. Such non-compliance may be unintentional (e.g., due to lack of understanding, knowledge, or commitment), or intentional (e.g., due to deliberate choice to ignore or compromise the requirements of any applicable regulation, organizational policy, or determination of the IRB)."*

2. *Review the History Tab of the Continuing Review*
   - Pre-Review analyst note in the History tab
   - Pre-Review Clarification responses and Added Comments from the Study Team
   - Review Comments entered by the other IRB member(s)
   - Private Comments entered by the IRB staff or members

3. *Reviewing other study related submissions in PROTECT to further understand the study*
   - Currently Approved Protocol and Consent Documents:
     - Review to understand the current state of the protocol only.
     - Available in the CR Workspace under the documents tab.
     - There is no need to review the different prior Modifications (MODs) since they have already been approved by the IRB.
   - Reportable New Events (RNIs):
     - **All reportable events since the last CR would have been summarized in the CR Smart Form**
     - RNIs that were reviewed by the NIH IRB will be viewable by IRB members. (This includes UPs.)
     - RNIs that were reviewed by OHSRP Leadership or the RCRC are not viewable by IRB members, and you will need assistance from the analyst if you have a need to review.
   - **Reminder: The approval of previous MODs and the determinations for the RNIs along with the review of the related corrective actions have already been made and cannot be revisited at CR.**

4. *Enter your reviewer's note into the system using the "add Review Comments" activity*
   - If you are an assigned reviewer, please enter a note even if it only states that you have no concerns.
   - Any IRB members that are not the assigned reviewer for a submission should also enter a review comment if they have a concern, if not, they are welcome to add a note stating they have no concerns but are not required to do so.

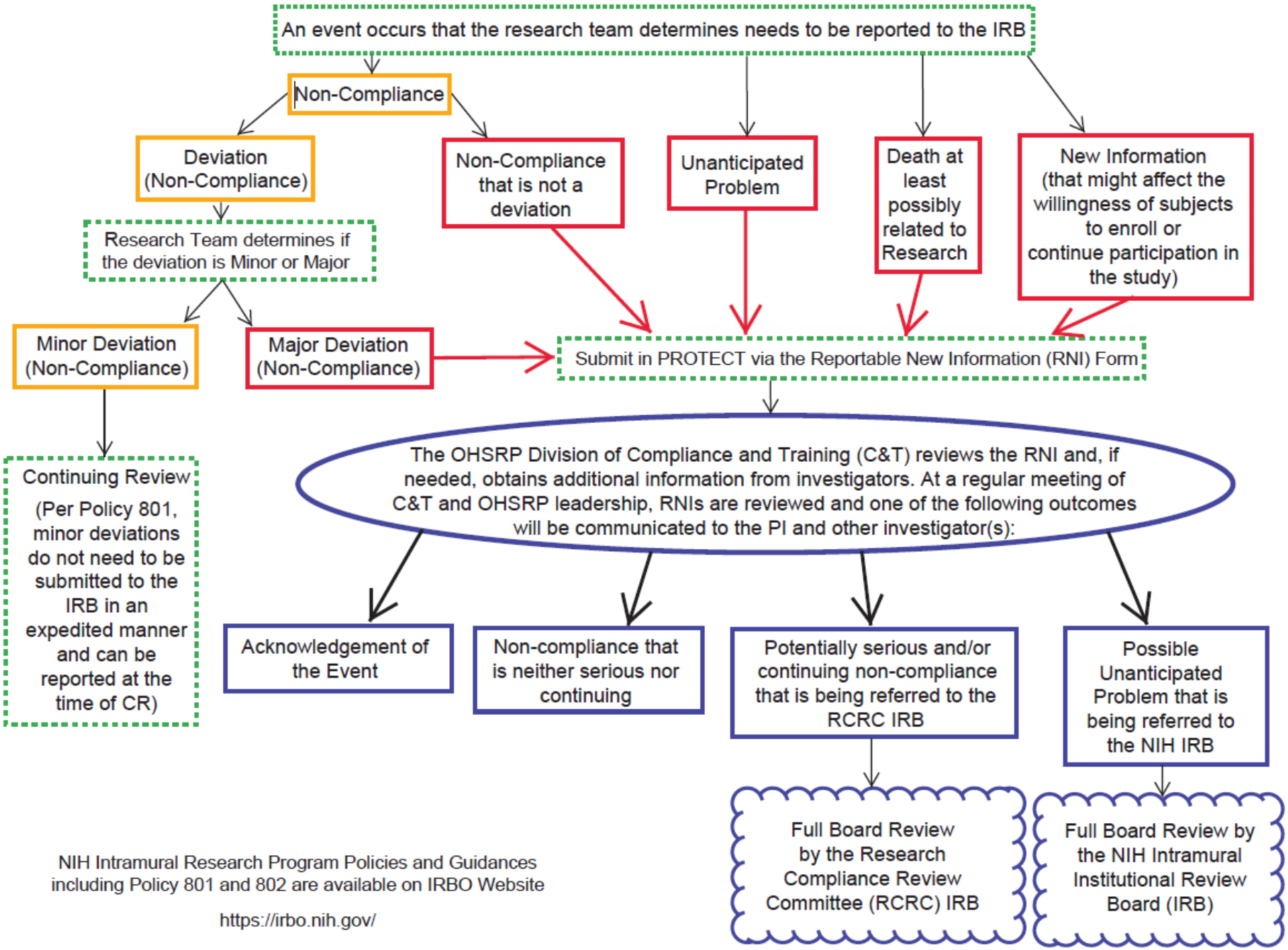
Presenting a CR during the IRB Meeting:

1. *Presentation of the Continuing Review by the Primary Review*
   - Presentation and discussion of a CR can only take a few minutes if there are no concerns to address.
   - Explanation of the protocol can be a few summary sentences, and there is no need to review every change in the last year.
   - Focus on items from the CR Smart Form that are not checked since they are relevant to the approvability of the protocol.
   - Remember that the other members also were required to review all the material relevant for the CR.

2. *IRB Determination and voting*
   - Focus on if the protocol meets the criteria for approval when discussing the determination.
   - If the IRB is requiring additional action before approval, pay attention to the protocol expiration date.
   - Consider if a shortened approval period may be sufficient to address certain concerns.
   - If the PROTECT submission is a CR only, changes to the consent or protocol cannot be made by the IRB during the meeting.
   - If the PROTECT submission is both a CR and a MOD, you cannot give separate determinations for each item.

Reportable New Information Flow Sheet Summary

Updated 6/5/2023



NIH Intramural Research Program Policies and Guidances including Policy 801 and 802 are available on IRBO Website

https://irbo.nih.gov/