Guidance
Continuing Review Submissions

General Considerations

- Continuing Review (CR) submissions (or 'packages') must be submitted NO LATER than 60-days before the expiration date. Ideally, if a CR requires full board review, it should be reviewed at the convened Institutional Review Board (IRB) meeting held the month **prior** to expiration to avoid potential lapse in the event the protocol would need to be tabled by the IRB because regulatory criteria for approval were not met.

- It is the **Principal Investigator's** (PI) responsibility to keep track of expiration dates and ensure that the progress report is submitted by the deadline. IRBNet will send out automatic reminders, however the onus is ultimately on the PI to keep track of this. Study lapses constitute non-compliance. The Research Integrity Manager will no longer be providing courtesy phone call or email reminders.

- Timing of Submissions: If a project is going to be modified, but it is close to CR deadline or there is a CR submission pending– it is preferable that the amendment submission wait until the CR is approved. However, if this is not possible (patient safety issue, sponsor deadline, etc.) please **contact the IRB Office early** so we can assess any special handling that will be needed in coordinating multiple submissions.

Completing the Continuing Review Form

This does not address every question on the form, rather, those which study teams seem to have the most questions or answer incorrectly most often.

- **Study Status:** As long as data analysis is continuing on identifiable or coded data, the study must remain open with the IRB. See OHRPs guidance for definitions for more information.

- **2 a-f:** Applies to **local** numbers, not study-wide.

    - Double check your calculations – the sum of sections c-f should equal b, "Total to Date."

    - Previous forms are sometimes used and old numbers are left in which are incorrect. Start fresh with new form and double check numbers in case anything was reported incorrectly in previous submissions.

- **2 a**: Enrollment number approved by the IRB; this is a good time to check if accrual is close to this limit and plan for an amendment, if needed.

Guidance
Continuing Review Submissions

- **2 g**: Real time data is preferred, however if enrollment information is provided by an external sponsor via monthly newsletter, email, etc. this number is acceptable.

- **2i and 4g:** Be sure these make sense and are consistent (for example, – if in question 2i it is reported that subjects have not been enrolled because English is not their primary language, question 4g should not indicate that non-English speaking individuals have been included).

- Complete section 2 **or** 3, not both. Section 2 pertains to studies that interact or intervene with subjects, section 3 pertains to studies that access data or specimens.

- **3 a-b and 2 a-b:** Question b should not be more than a; if it is, this means that the study has enrolled more subjects than the IRB approved. A report of this deviation must be submitted, as well as an amendment to increase enrollment (unless study is closed to accrual).

- If the CR is one of several in a row in which there very low or no enrollment (compared to what was expected) the IRB may question this and may ask for rationale for continuing the study. It would be helpful if an explanation could be provided at the time of submission. A future update of the CR form will include more questions to address low enrollment.

- Alternatively, if a study is completed and has been in data analysis in several years with no progress or interim conclusions the IRB may question this.

- **4e**: "Directly awarded" means the investigator is the named grant awardee and receives the grant funds directly (not through a sub-contract with another institution or consortia group).

- **4F**: Relates to Investigator Initiated research, not industry or consortia studies.

- **4I:** if any of these are checked "yes" - do not forget to **also describe** below the table (as asked for on the form) and include any applicable additional documentation (reportable event log, monitoring reports, etc.).