# Instructions for Completion of the eBridge CPR SmartForm

1. Log into eBridge, locate the study
2. In the Study Workspace, in the Left Navigation area, select New Continuing Progress Report button.

**Page 1:**
1.1 – 1.6: Respond to questions appropriately

**A1.** Projects Involving Direct Contact – Interaction or Intervention – with Subjects or Use of Consent Forms:
A1.1: Choose the best option to describe the current status of the study. Note that subjects followed only for recurrence, mortality or quality of life are not considered "active"

B1.1: Choose the best option to describe the current status of the study.

**Page 2:**
2.1: Respond "No", unless the CPR is submitted after the study has expired.

**Page 3:**
3.1 – 3.4: Complete only if the answer to 2.1 is "Yes"

**Page 4:**
4.1: Only complete for chart review or biospecimen collection studies

- All fields must contain a number (enter "0" if none)

**The MCW/FH IRB defines collection and review to include any samples or records that were accessed, looked at, or used for the purposes of the study.** Review of records to determine eligibility should not be recorded here.

4.1.1 & 4.1.2:

- For the 1st CPR - enter zeros under "Since Last CPR" and enter the total number of samples collected or charts reviewed since the start of the study under "Since Initial Approval".
- For the 2nd or later CPR - enter the number of samples collected or charts

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**The MCW/FH IRB defines enrollment or accrual to include any subject that has gone through a consent process and has signed a consent form regardless of the level of participation in the study that occurs after the consent form is signed.**

- For the 1st CPR - enter zeros under "Since Last CPR" and the number of subjects in the appropriate category based on their status under "Since Initial Approval"
- For the 2nd or later CPR - enter the number of subjects enrolled only during this reporting period under "Since Last CPR".
- For 2nd or later CPR - add the number of subjects enrolled for the entire study plus those enrolled during this reporting period under "Since Initial Approval".
- "Since Initial Approval" is a cumulative section

5.1.1: This section refers to the number of subjects who were screened or whose records were reviewed before informed consent was obtained. For projects in which "waiver to document informed consent" was approved, "0" can be entered as the number of subjects signing consent forms.

5.1.2: This section refers to the number of subjects who signed a consent form to participate in the study.

*Example: The study team "screened" or considered 120 subjects or records for the study (enter this number in Section 5.1.1) but only enrolled 98 participants (enter this number in Section 5.1.2) because the remaining 22 subjects or records were not eligible or not interested in participating in the study.*

5.1.3: This section refers to the number of subjects who remain enrolled in the study and are actively completing study procedures as defined in the study protocol (e.g. scheduled interventions, questionnaires, blood draws, etc.).

**Follow-up is defined as the point in the study where there is no ongoing research-specific intervention and the only activities remaining are ascertaining morbidity or mortality, Quality of Life questionnaires, and/or accessing ongoing medical records.** Subjects in follow-up are not considered active and not considered completed; therefore please explain the number of subjects in follow-up in section 14.1.

5.1.4: This section refers to the number of subjects who have completed all of the following; active study interventions described in the protocol, or have met an endpoint such as death, and no more study-specific data is being collected for these subjects.

5.2: This section applies to studies that did not enroll any subjects since the last CPR.

5.3, 5.3.1, 5.4, & 5.4.1: Respond to questions appropriately.

5.5: This question automatically populates, no action is necessary.

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**Page 6:**
6.1 – 6.2: Comes up only if a closed to enrollment category was selected in A1.

6.1: Enter the date that study stopped enrolling subjects.

6.2, 6.2.1, 6.2.1.1: Complete as appropriate to the study.

**Page 7:**
7.1 –

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17.1: Go to the main Study Workspace, click on the Amendments tab and look to see if any amendments have been approved since the last CPR. If yes, then complete 17.1.1.

17.1.1 – Provide the amendment number and a brief description of the amendment (i.e., AME00005367, Extend study duration, add a member to the study team.)

17.2: Enter a "Yes" or "No" response for any amendments that have been submitted to the IRB but have not been approved yet.

**Page 18:**

18.1: Upload the current consent form(s); publications, abstracts, poster presentations; protocol deviation summaries; internal and external audit reports; site visit reports, DSMB/DMC reports, and any other required documents for review.

**Page 19:**

1-2: Review instructions

**Submit Continuing Progress Report:**

1. In the CPR Workspace, the Investigator must select the "Submit to IRB" link located in the Left Navigation under the My Activities section.