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: Projects NOT Involving Direct Contact – Interaction or Intervention – with Subjects and NOT Using Consent Forms *Use this page for chart review and biospecimen collection studies.*
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 reviewed since the last CPR (only those collected/reviewed during this reporting period) under "Since Last CPR".
- For the 2nd or later CPR - add the number of samples collected or charts reviewed for the entire study (those collected/reviewed since the beginning of the study plus those collected/reviewed during this reporting period) under "Since Initial Approval".
- "Since Initial Approval" is a cumulative section

Page 5:
5.1.1 – 5.1.4: Only complete for studies that have direct contact with subjects or use consent forms.

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

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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.

Instructions for Completion of the eBridge CPR SmartForm

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 – 7.6: Only complete for studies that have direct contact with subjects or use consent forms.

- All fields must contain a number (enter "0" if none)
- For the 1st CPR - enter zeros for 7.1, 7.2, & 7.3 under "Since Last CPR" and the number of subjects in the appropriate category since the start of the study under "Since Initial Approval".
- For the 2nd or later CPR - enter the number of subjects withdrawn or who have died during this reporting period under "Since Last CPR".
- For the 2nd or later CPR - add the number of subjects withdrawn or who have died for the entire study plus those during this reporting period under "Since Initial Approval".
- "Since Initial Approval" is a cumulative section

7.1: This section refers to the number of subjects withdrawn by the PI after signing the consent form, due to becoming ineligible (screen failures), non-compliance, the PI believes that it is in the subject's best interest to withdraw, such as due to adverse response or lack of response to the drug or device, needing a drug not allowed per protocol, etc.

7.2: This section refers to the number of subjects who choose to withdraw voluntarily due to any reason (time constraints, moved, no longer interested, etc.)

7.3: This section refers to the number of subjects who have died during the active phase of the study, that is, during procedures described in the protocol. It does not matter if the death was related to the study or not; the reasons for death should be documented in Section 14.1. If a subject died during long-term follow-up, do not count in this section, but please explain in section 14.1.

7.4: Enter the reason for each subject withdrawn by the Investigator since the last CPR (include screen fails if consent form was signed, becoming ineligible after signing a consent form, noncompliance with study procedures, adverse response, etc).

7.5: Enter the reason for each subject who chose to no longer participate in the study for any reason since last CPR.

7.6: Complete as appropriate to the study.

Page 8:

8.1 – 8.2: Comes up if you answer "Yes" on last question of Page 7. Complete and if you have any questions, discuss them with IRB Coordinator II for the study.

Instructions for Completion of the eBridge CPR SmartForm

Page 9:
9.1: Respond to questions appropriately and upload summary or log of events (both internal and external, if applicable). The summary should include Reportable Events reported to the IRB since the last CPR, as well as events that did not require immediate reporting.

Page 10:
deleted

Page 11:
11.1: This question automatically populates, no action is necessary.

Page 12:
12.1: This question automatically populates, no action is necessary.

12.2: The date may be changed in 12.2. If the date is extended or made longer, you must submit an amendment to seek approval for the extended date of completion.

Page 13: (Only comes up if submitting a final report to close the study)
13.1: Enter the date that all study activities were completed.

13.2 – Complete as appropriate to the study.

13.2.1 – Enter a statement.

13.3: Respond to the two points in the question, if applicable.

Page 14:
14.1: Explain what has happened during this reporting period. This is the section where other interesting data/facts can be explained regarding subjects or the conduct of the study that don't fit in other sections, including any subject deaths.

14.2: Only for multi-center studies; copy & paste sponsor-provided information.

Page 15:
15.1 – 15.2: Respond to questions appropriately

Page 16:
16.1: Provide a summary about any serious concerns raised by site visits, reviews, and internal or external audits. Documentation of these concerns should be uploaded into Section 18.

16.2: (Only for studies that have a Data Safety Monitoring Board (DSMB), Data Monitoring Committee (DMC) or Data Monitoring Plan)
Provide a summary of information provided by the DSMB/DMC for the study. Documentation of DSMB/DMC review, evaluation, and findings should be uploaded into Section 18.

Page 17:

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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.