CONTINUING REVIEW: SITE-SPECIFIC UPDATE

Study Information	
Study Title:	
Emory IRB Number:	
Site Name:	
Site PI:	

1. **Were there any "significant new findings"* during the past approval period at your site?** You must give the Emory study team a summary of your site findings during the past period.
   Yes ☐ **No** ☐
2. **If yes, note any findings below that may have affected the willingness of subjects to enroll*/continue participation.**

3. **Are you continuing to enroll* new subjects or obtain charts/data/specimens for NEW subjects (check below)?**

Enrolling New Subjects ☐ **Chart reviews** ☐ **Obtaining data/specimens** ☐ **None of these** ☐

4. **If your site's activities only involve chart review, medical records, or data analysis:**
   Enter the number of charts/records/specimens analyzed to date.
5. **If your site was or is currently enrolling*:**
   a. **How many NEW subjects have been enrolled* at your site in the past approval period?**

Gender	**Number of Males:** **Number of Females:** **Unknown or data not collected** ☐
Vulnerable Populations	**Number of pregnant women:** **Number of children:** **Number of prisoners:** **Number of cognitively-impaired individuals:** **Number of non-English speakers:** **None of the above** ☐

   b. **Indicate the age groups of the population enrolled* during the past approval period.**
   ☐ **Less than six years old** ☐ **11 - 17 years old** ☐ **Over 89 years old**
   ☐ **6 - 10 years old** ☐ **18 years and older**
   c. **How many subjects were withdrawn during the past approval period?** You must give the Emory study team a summary of these withdraws for the CR submission.
   d. **Explain any difficulties you've had at your site with recruiting or retaining subjects.**

   e. **What's the total number of subjects who have given informed consent at your site to date?**

   f. **How many subjects at your site completed required screening and began treatment/intervention/participation to date?**

* Check researcher guidance form "Submitting a CR Progress Report for a Multi-site Study for clarification of this term.

6. **If the site is now closed to enrollment*:**
    a. **What date was the site closed?**
    b. **What was the enclosure reason?**
    c. **What are the remaining research-driven interventions/interactions at this site, if any?**

7. **How many of the following events occurred at the relying site:**

Unanticipated problems related to study involving risk to participants/others?	
Serious adverse events definitely/probably/possibly related to study?	
Internal deaths related to study participation?	
Anticipated events with greater frequency, duration, or severity than described in documents?	
Substantive protocol deviations or noncompliance affecting the rights, welfare, safety, willingness to participate, or integrity of the data?	
Complaints affecting subjects' rights, welfare, safety, or their willingness to participate?	

8. **Have all reportable events been reported to Emory IRB as required in this approval period (either previously or in this renewal)?**
    Yes ☐ **No** ☐ **No new significant findings** ☐

9. **Is there any other information that was not previously reported before by this site, not fitting the above-described criteria that needs to be reported?**
    Yes ☐ **No** ☐

10. **Has any agency (FDA, OHRP, etc.) audited, inspected, or otherwise monitored this study site during the past approval period?** **You must give the Emory study team correspondence or reports to upload to the CR submission.**
    Yes ☐ **No** ☐

11. **Are there any new conflict of interest disclosures that were made to the COI office in the past approval period?** **You must give the Emory IRB any new or updated management plans.**
    Yes ☐ **No** ☐

12. **Have you confirmed that all study team training required by the institution is up to date?**
    Yes ☐ **No** ☐

* Check researcher guidance form "Submitting a CR Progress Report for a Multi-site Study for clarification of this term.