Non-VA Continuing Review / Closure Attachment

Study Information

Study # | Principal Investigator Name | Principal Investigator E-mail | Principal Investigator Phone |
--------|-----------------------------|-------------------------------|----------------------------|
         |                             |                               |                            |
Type of Research (check all that apply) | Primary Contact Name | Primary Contact E-Mail | Primary Contact Phone |
☐ FDA  ☐ CTSC |                               |                               |                            |
☐ CRTC… CTSU Form is: ☐ attached ☐ not attached | Funding Source (Sponsor): | | |

1. * What is the local approved target enrollment? _____
2. What is the all-sites approved target enrollment? (If applicable) _____
3. * What is the enrollment status of the study? 
   ☐ Open to Enrollment
   ☐ Closed to Enrollment
4. * If the study is closed to enrollment, what, if any, interventions continue? _____
5. * If this study requires a Data and Safety Monitoring Board, please provide the most recent report.
   ☐ Report attached
   ☐ Report not attached. Please clarify: _____

Please answer the following RA questions ONLY IF you are requesting to:
1. reactivate an expired or previously closed study OR
2. close an expired study

RA1. * When was the last HRRC/IRB Approved to Date? _____

RA2. * Has the Study Sponsor or Funding Agency been notified of the lapse in approval? 
   ☐ Yes, documentation attached  ☐ No  ☐ N/A
   If No, explain: _____

RA3. * What research-related activities have occurred since the study expiration date? 
   ☐ No research-related activities have occurred.
   ☐ The following research-related activities have occurred:
     ☐ Subjects have been enrolled or records/specimens reviewed.
     ☐ Treatments/Interventions have been administered.
     ☐ Follow-up activities have been conducted.
     ☐ Data have been obtained.
     ☐ Other Research Activities not reported above have occurred.
   If you marked any of these statements, please submit each occurrence/event as a protocol violation using the Reportable New Information Form.
Please answer the following C questions ONLY IF you are requesting to close the study:

C1. * What is the status of the study?
   - Study never began (no research related activities occurred to date)
   - Local enrollment is closed, local research related interventions are complete, and participant follow-up is complete

C2. * Which of the following is true regarding data analysis?
   - Data analysis is complete
   - Data analysis continues locally; no links to identifiers remain
   - This is a multi-center trial and data analysis is not being done at this site

C3. * How were data collected for the study?
   - Data Collection Forms/Case Report Forms
   - Transcribed Interviews
   - Personal Computer Database
   - Web-based/Online Data Entry
   - Video/Audio Tape
   - Transcribed Focus Group
   - Other: (describe) _____

C4. * How were data linked to individual participants?
   Describe:
   _____

C5. * Are the data de-identified?
   - Yes, Data are de-identified.
   De-identification process was completed on: _____
   Describe the process used to de-identify the data:
   _____
   Destruction of the link was completed on: _____
   Describe the process used to destroy the link to identifiers:
   _____

   - No, Data remain identifiable per prior HRRC or IRB Approval.
   Justify retention of identifiable data:
   _____
   Describe procedures that are in place to protect confidentiality of any identifiable data (including storage and security for electronic and hard copies):
   _____