DHA Protocol Continuing Review

Please complete this template and upload it, along with all supporting documentation, to your project in IRBNet.
*(**You may need to click "Enable Editing" on the yellow bar above in order to complete this template**)*

Submission Date: (Submit completed template to dha.ncr.dha-cs-mgt.mbx.hrpp@mail.mil)

1. Study Information:

Full Study Title:		
CDO #: [1]	**IRBNet #:**	**Vendor #:**
Principal Investigator:	**PI Affiliation:**	
PI Phone:	**PI email:** [2]	
Government Project Manager:	**GPM Affiliation:**	
GPM Phone:	**GPM email:**	

[1]found on original approval memo
[2]professional email (no gmail, yahoo, hotmail)

2. Changes to Study:

Have there been changes to the study design?[3] ☐ Yes ☐ No
If "yes," then please describe the changes:

[3]examples: title change, increase or decrease in number of subjects, scope of work, addition or removal of sites, *etc*.

Do any of these changes increase the level of risk to subjects? ☐ Yes ☐ No ☐ N/A

Have there been staff changes?[4,5] ☐ Yes ☐ No

If "yes," then please provide the following information for each:

Name: Affiliated Institution:	Study Role:	Date of CITI Training:
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[4]examples: change in PI or Government Project Manager, addition or removal of associate investigators, change in Medical Monitor, *etc.*
[5] for each new staff member, you MUST provide documented proof of successfully completing CITI training within the past 3 years

3. Justification for Request to Continue:

Please provide a brief explanation for why you wish to continue work on this activity:

4. Current Study Status:

Preliminary Results/Progress Report
Please provide a concise summary that includes preliminary findings, obstacles/challenges, progress toward completion and timeline for completion (best guess):

Publications and Presentations		
Have any results from this activity been *Published* during this review period?	☐ Yes	☐ No
If "yes," then provide citation(s):		
Are any manuscripts currently under development or in clearance for *Publication*?	☐ Yes	☐ No
Have any results from this activity been Presented during this review period?	☐ Yes	☐ No
If "yes," then provide the venue(s)/event(s)/conference(s):		
Are any abstracts currently under development or in clearance for *Presentation*?	☐ Yes	☐ No

Status of Data Collection			
Number of subjects about whom data have been collected:		If "zero," then please explain:	
Gender Breakout:	# males:	# females:	# Unknown:

Status of Subject Recruitment/Enrollment			
Number of subjects *Recruited*:		Number of subjects *Enrolled*:	
Gender Breakout:	# males:	# females:	# Unknown:

Enrollment of Potentially Vulnerable Populations in the Study: *(check all that apply)*

- ☐ Military Personnel
- ☐ Children (under the age of 18 years…except active duty service members who are considered adults irrespective of age)
- ☐ Decisionally-impared Adults
- ☐ Prisoners
- ☐ Pregnant Women
- ☐ Fetuses or Newborns

Subject Withdrawals or Complaints	
Have any subjects withdrawn or been withdrawn for any reason after signing a consent form? ☐ Yes ☐ No	
If "yes," then please note the total number (for this review period) withdrawn for each category below:	
Number Withdrawn	**Category/Reason**
	Screen Failure
	Subject's Request to Withdraw
	Subject's Medical Status
	Treatment Toxicity
	Subject's Non-Compliance
	Investigator's Discretion
	Disease Progression
	Lost to Follow-up
	Death
Have any subjects complained about any aspect of the study during this review period? ☐ Yes ☐ No	
If "yes," then please provide the number of complaints and a brief description of each:	

5. Deviations from Originally Approved Study Design

Have there been any deviations from the approved study design during this review period?	☐ Yes	☐ No
If "yes," then please provide an explanation of each:		

6. Unanticipated Problems and Adverse Events

Have there been any unanticipated problems or adverse events during this review period: ☐ Yes ☐ No

If "yes," then please provide the following information (use attachments as necessary)

Date Occurred	Date Reported to IRB	Number Affected	IRB Action
Brief Description of Event:			

Date Occurred	Date Reported to IRB	Number Affected	IRB Action
Brief Description of Event:			

Date Occurred	Date Reported to IRB	Number Affected	IRB Action
Brief Description of Event:			

Completed by: (Insert Principal Investigator's Attestation in the Boxes Below)

Name:

Institutional Affiliation:

Work email Address:

Date Completed: