**ANNUAL PROGRESS REPORT**

**RESEARCH ETHICS REVIEW COMMITTEE**

**1. Details of the Lead Investigator**

|  |  |
| --- | --- |
| Name: |  |
| Address: |  |
| Telephone: |  |
| E-mail: |  |
| Fax: |  |

**2. Details of study**

|  |  |
| --- | --- |
| Full title of study: |  |
| RERC reference number: |  |
| Date of favorable ethical opinion: is that the name or is it RERC approval? |  |
| Sponsor: |  |

#### 3. Commencement and termination dates

|  |  |
| --- | --- |
| Has the study started within DHCC? | [ ]  Yes [ ]  No  |
| If yes, what was the actual start date? |  |
| If no, what are the reasons for the study not commencing?What is the expected start date? |  |

|  |  |
| --- | --- |
| Has the study finished?*If yes, complete and submit the “Declaration of end of trial” form*  | [ ]  Yes [ ]  No  |
| If no, what is the expected completion date?*If you expect the study to overrun the planned completion date this should be notified to the main RERC for information.* |  |
| If you do not expect the study to be completed, give reason(s) |  |

**4. Site information**

|  |  |
| --- | --- |
| Number of DHCC research sites proposed in original application:Number of DHCC research sites recruited to date: |  |
| Do you plan to increase the total number of DHCC sites proposed for the study?*The addition of any new sites not listed in the original applications to the RERC should be notified by submitting a substantial amendment using the form*  | [ ]  Yes [ ]  No  |

**5. Recruitment of participants**

|  |  |
| --- | --- |
| \* Number of participants recruited: | *Proposed in original application:**Actual number recruited to date:* |
| \* Number of participants completing trial: | *Actual number completed to date:* |
| \* Number of withdrawals from trial to date due to: |
| (a) withdrawal of consent  |  |
| (b) loss to follow-up |  |
| (c) death (where not the primary outcome) |  |
| Total study withdrawals: |  |
|  |  |
| \*Number of treatment failures to date (prior to reaching primary outcome) due to:  |  |
| (a) adverse events |  |
| (b) lack of efficacy |  |
| Total treatment failures: |  |

*\* In the case of international trials, please provide separate figures for DHCC, UAE and global recruitment .*

|  |  |  |
| --- | --- | --- |
| Have there been any serious difficulties in recruiting participants? |  | Yes / No |
| If yes, give details: |  |  |
| Do you plan to increase the planned recruitment of participants into the study?*Any increase in planned recruitment should be notified to the RERC as a substantial amendment for ethical review.* |  | Yes / No |

6. Safety reports

|  |  |
| --- | --- |
| Have there been any Suspected Serious Adverse Events as per the DHCR definition? E.g. unexpected Serious Adverse Reactions (SUSARs) in this trial? | [ ]  Yes [ ]  No  |
| Have these been notified to the RERC within 7/15 days?*If no, please arrange urgently and give reasons for late notification.* | [ ]  Yes [ ]  No  |
| What is the reporting date for periodic safety reports to the RERC during this trial? |  |
| Has a 6 monthly safety report been submitted? | [ ]  Yes [ ]  No [ ]  Not yet due  |
| Has the Annual Safety Report been submitted? | [ ]  Yes [ ]  No [ ]  Not yet due  |
| When is the next ASR due? | DD/MMM/YYYY |

**7. Amendments**

|  |  |
| --- | --- |
| Have any substantial amendments been made to the trial during the year? | [ ]  Yes [ ]  No |
| If yes, please give the date and amendment number for each substantial amendment made. |  |

**8. Serious breaches of the protocol or Good Clinical Practice**

|  |  |
| --- | --- |
| Have any serious breaches of the protocol or GCP occurred in relation to this trial during the year?*all serious breaches must be notified to DHCR within 7 days of the matter coming to the sponsor’s attention.* | [ ]  Yes [ ]  No |
| If yes, please give the date of each notification to the DHCR.*Please provide the RERC with a copy of each notification for information (unless previously notified).* |  |

**9. Other issues**

|  |  |
| --- | --- |
| Are there any other developments in the trial that you wish to report to the RERC?Are there any ethical issues on which further advice is required?*If yes to either, please attach separate statement with details.* | [ ]  Yes [ ]  No[ ]  Yes [ ]  No |

**10. Declaration**

|  |  |
| --- | --- |
| Signature of Lead Investigator: |  |
| Print name: |  |
| Date of submission: |  |