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| **FORM 3.2 PROGRESS REPORT** |

|  |  |  |  |
| --- | --- | --- | --- |
| URERC Protocol Number |  | Date of Approval |  |

|  |  |
| --- | --- |
| Title |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Principal Investigator/ Researcher |  |  | Received by:Name & Signature |
|  |  |  |  |
| Sponsor |  |  | Date Received: |

**ACTION REQUESTED:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  | **For Quarterly Reports** |  |  | **For Annual Reports** |
|  |  |  |  |  |  |
|  |  | For Notification Only |  |  | Renew - New Participant Accrual to Continue |
|  |  |  |  |  |  |
|  |  | Terminate - Protocol Discontinued |  |  | Renew - Enrolled Participant Follow Up Only |
|  |  |  |  |  |  |
|  |  |  |  |  | Terminate - Protocol Discontinued |
|  |  |  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| 1. | Any amendment **to the protocol** since the last review?  |  |  |
|  |  | Yes |  | No |  | Describe briefly:  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 2. | Any change in participant population, recruitment or selection criteria since the last review? |
|  |  | Yes |  | No |  | Explain the changes |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 3. | Any change in the Informed Consent process or documentation since the last review? |
|  |  | Yes |  | No |  | Explain the changes:  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 4. | Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? |
|  |  | Yes |  | No |  | Discuss and attach a narrative: |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 5. | Any unexpected complication or side effect noted since the last review? |
|  |  | Yes |  | No |  | Discuss and attach a narrative: |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |  |

|  |  |
| --- | --- |
| 6. | Did any participant withdraw from this study since the last approval? |
|  |  | Yes |  | No |  | Reasons for withdrawal: |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 7. | Any new investigator that has been added to or removed from the research team since the last review? |
|  |  | Yes |  | No |  | Please identify them and submit the CVs of new investigators: |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 8. | Are there any new collaborating sites that have been added or deleted since the last review? |
|  |  | Yes |  | No |  | Please identify the sites and note the addition or deletion: |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |  |

**SUMMARY OF PROTOCOL PARTICIPANTS**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Since the Study Started** | **For the Quarter Only** | **For the Year** |
| **Total Screened** |  |  |  |
| **Total Screened Failures** |  |  |  |
| **Total Re-screened** |  |  |  |
| **Total Randomized** |  |  |  |
| **Total Completed** |  |  |  |
| **Total Early Termination** |  |  |  |

*To be filled out by URERC Primary Reviewer*

**RECOMMENDATIONS:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|   |  |  |  |  |  |
|  |  | **For Quarterly Reports** |  |  | **For Annual Reports** |
|  |  |  |  |  |  |
|  |  | Noted and Accepted |  |  | Approved |
|  |  |  |  |  |  |
|  |  | Request further information |  |  | Request an amendment to the protocol  |
|  |  |  |  |  |  |
|  |  | Suspend or terminate the study |  |  | Request an amendment to the Consent Form |
|  |  |  |  |  |  |
|  |  |  |  |  | Request further information |
|  |  |  |  |  |  |
|  |  |  |  |  | Suspend or terminate the study |
|  |  |  |  |  |  |

|  |  |  |
| --- | --- | --- |
| Changes to the Protocol recommended: |  | Comments: |
|  |  |  |  |  |  |
|  |  | Yes |  | No |  |
|  |  |  |  |  |  |

|  |  |  |
| --- | --- | --- |
| Changes to the Informed Consent Form recommended: |  | Comments: |
|  |  |  |  |  |  |
|  |  | Yes |  | No |  |
|  |  |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Primary Reviewer |  | Signature |  | Date |
|  |  |  |  |  |

|  |  |
| --- | --- |
| URERC Final Decision |  |

Certified by:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Chair |  | Signature |  | Date |
|  |  |  |  |  |