**PROTOCOL DEVIATION / VIOLATION**

Return this form to: Baptist IRB [Baptist.IRB@bmhcc.org](file:///\\MTCCBMHFP\PUBLIC$\Clinical\BCRI\IRB\IRB\IRB%20Administrative%20Operations\Current%20Forms\Latest%20IRB%20Forms%202018\IRB%20Applications\Revised%20Applications%206-1-18\Baptist.IRB@bmhcc.org) (Baptist IRB)

Investigators and members of research teams who discover noncompliance within their own research activities are required to *self*-report the noncompliance to the IRB. If the investigator determines that the noncompliance meets the criteria for serious or continuing noncompliance, then the investigator must notify the IRB within five (5) days or as soon as practicable of making the determination. Noncompliance that does not meet the criteria for serious or continuing noncompliance should be reported at continuing review. **Reference: S.HRPP.1216 Research Noncompliance**

| Planned Deviation? | Yes  No  Unknown |
| --- | --- |
|  | Emergency  Non-Emergency |
| Noncompliance | Serious  Continuing |

**Study/Site Information**

| Date: |  |
| --- | --- |
| Baptist-IRB Number: |  |
| Protocol Title: |  |
| Principal Investigator: |  |
| Research Study Coordinator: |  |
| IDE or IND Number: |  |
| NCT Number: |  |
| Protocol Number: |  |
| Sponsor: |  |
| Study Status: | Open to Enrollment  Closed to enrollment but currently enrolled subjects are receiving active treatment and /or completing follow-ups.  Study closed to enrollment, subjects only undergoing follow-up assessment.  Data Analysis only. |
| Person completing this form: | Name:       Phone:       Email: |

**Subject Information**

|  |  |
| --- | --- |
| Subject ID and Initials: |  |
| Study Number: |  |
| Subject Status: | Active  Follow-up  Withdrawn  Deceased |
| Date of Unanticipated Problem (Event): |  |
| Has the sponsor been notified of the event: | Yes  No  N/A If no, date sponsor will be notified |

**Report Information**

|  |  |
| --- | --- |
| Date of Deviation: |  |
| Deviation Explanation: | Enrollment Process  Consent Process (oral or written)  Drug/Device Administration  Other Protocol Activities  Audit Finding that Requires Corrective Action  Out of Window  Other (Specify) |
| Deviation Reason: |  |
| Action Taken: |  |
| Date Aware of Deviation: |  |

| Does sponsor require reporting to the IRB?  Comment: | Yes  No  Unknown |
| --- | --- |
| Does the deviation affect/change the risk/benefit ratio for subjects?  Comment: | Yes  No  Unknown |
| Does the deviation affect the integrity of the research?  Comment: | Yes  No  Unknown |
| Does the deviation affect the subject’s willingness to continue study participation?  Comment: | Yes  No  Unknown |

**Follow-Up**

| Resolution: |  |
| --- | --- |
| Corrective Action Plan: |  |

**I hereby certify that I have fully disclosed all information pertaining to this event and that the information above is accurate.**

| Submitting Signature (Principal Investigator or Sub Investigator) | | |
| --- | --- | --- |
|  |  |  |
| Name |  | Title |
|  |  |  |
| Signature |  | Date |

**\*\*\*\*FOLLOWING SECTION IS TO BE COMPLETED BY IRB CHAIR OR DESIGNATED REVIEWER\*\*\*\***

| Initials |  |
| --- | --- |
|  | Further Investigation Required  Information Requested |
|  | The above protocol deviation/violation meets the criteria of serious continuing noncompliance.  Yes – Referred for Review at a Convened IRB Meeting  No – Acknowledged: No action required |

**I do not have any personal, scientific or financial conflict with this project.**

| **Baptist IRB Chair or Designated Reviewer** | | |
| --- | --- | --- |
|  |  |  |
| Name |  | Title |
|  |  |  |
| Signature |  | Date |