**SAFETY REPORTING FORM**

Return this form to: Baptist IRB [Baptist.IRB@bmhcc.org](mailto:Baptist.IRB@bmhcc.org) (Baptist IRB Memphis)

**Policy**

Problems occurring in the course of clinical research that in the judgment of the investigator meet federal criteria for *Unanticipated Problems Involving Risks to Subjects or Others* must be reported promptly to the Institutional Review Board. **Reference: S.IRB.1252 Unanticipated Problems Involving Risks to Subjects or Others.**

**Protocols overseen by Baptist IRB**

Any event that in the judgment of an investigator meets the criteria for a UPIRSO must be reported to the Baptist IRB of record within five (5) working days.

**Protocols overseen by an external IRB**

Investigators must follow the reporting requirements of the IRB of record. The investigator must inform the Executive Director of Baptist Clinical Research Institute of any *determination* by the external IRB of a local UPIRSO.

**Study/Site Information**

| Date: |  |
| --- | --- |
| BMH-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: | 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. |
| 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 Site Notification: |  |
| Event Details:  (check all that apply) | UPIRSO – OHRP considers unanticipated problems an event that include any incident, experience, or outcome that meets **all** of the following criteria:     1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; 2. related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and 3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.   Unanticipated adverse device effect means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.  Other, please specify |
| Event Explanation: | *Provide a detailed description of the unanticipated event, including how the event places the subjects or others at increased risk and how it has been resolved.* |
| Does this event require modification of the protocol, informed consent, or any other study related materials (e.g., Investigator Brochure, Recruitment Materials, etc.)?  YES  NO *If yes, please list and describe* | |
| Corrective Action Plan: | *Describe corrective measures that have been put in place to avoid re-occurrence:* |

**Investigator Opinion**

|  |  |
| --- | --- |
| Is this event related to participation in the research study? | YES  NO |
| Does this event have substantial adverse event on the safety or welfare of the study subject? *If yes, please describe* | YES  NO |
| Were changes or action taken to eliminate apparent immediate hazards to subject prior to IRB notification?  *If yes, please discuss changes or action taken* | YES  NO |
| Does this event have substantial adverse effect on the value of the data collected? | YES  NO |
| Is this event unexpected in terms of nature, severity or frequency? | YES  NO |
| Does this event, experience, or outcome place the subject at greater risk of economic or social harm than previously known or recognized?  *If yes, please describe* | YES  NO |
| Do you expect this event to occur again? | YES  NO |
| Do you believe currently enrolled subjects need to be notified of this event? | YES  NO |
| Should the protocol or consent form be modified as a result of this event?  *If yes, please submit your recommended changes.* | YES  NO |

**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 Only): | | |
| --- | --- | --- |
|  |  |  |
| Print Name |  | Title |
|  |  |  |
| Signature |  | Date |

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

|  |  |
| --- | --- |
| (initials) | In determining the appropriate response to a UPIRSO, the IRB may consider the following actions at a minimum: |
|  | No action (*e.g., when the event was self-limited, not likely to reoccur and no person was at fault*) |
|  | Require modification of the research protocol |
|  | Require modification of the information disclosed during the consent process |
|  | Require additional information be provided to past participants |
|  | Require notification of current participants (required when such information may relate to participants’ willingness to continue to take part in the research) |
|  | Require that current participants be asked to re-consent to participation |
|  | Modify the continuing review schedule |
|  | Monitor the research or monitor the consent process |
|  | Suspend or terminate approval for the research; (which would activate procedures described in the Policy *Suspension or Termination of IRB Approval of Research*). |
|  | Refer the matter to the organizational entities (*e.g., Risk Management, Corporate Compliance or the Privacy and Security Committee)* |

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

| BMHCC-IRB Chair or Designated Reviewer | | |
| --- | --- | --- |
|  |  |  |
| Print Name |  | Title |
|  |  |  |
| Signature |  | Date |