**SAFETY REPORTING FORM**

Return this form to: Baptist IRB 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 |