UCLA webIRB

Institutional Review Board Meeting Minutes

Medical IRB 3 meeting on (3/9/2017)
Grand Conference Room 820

Introduction

Date/Time of Meeting:
3/9/2017

Location of Meeting:
Grand Conference Room 820

Education/Past Meeting Minutes/Other
January 26, 2017 MIRB-3 Meeting Minutes

February 23, 2017 MIRB-3 Meeting Minutes

1-26-17 MIRB-3 Meeting Minutes.pdf
2-23-17 MIRB-3 Meeting Minutes.pdf

Minutes Prepared By: [redacted]

Important Notes:

1. The ***approval period*** for each new or continuing study is one year minus one day from the date of this meeting. If the approval period is less than this, the period is noted in the minutes. Otherwise, it is not.
2. All applications are reviewed according to the ***criteria required by federal regulations*** for IRB approval of a human research study. These criteria are available to all members at the meeting.
3. If a study is Accepted Pending Modification, Deferred or Disapproved, the specific IRB requests and the basis for the requests are indicated in the ***attached correspondence*** to the investigators.
4. If ***controverted issues*** are discussed and/or ***conditions are imposed*** on the approvals, that discussion or information is described above the motions and the votes for each study listed. If neither is discussed, then only regulatory determinations, as appropriate, and the motions are noted for each study.
5. If an IRB member has a conflict of interest on a study being reviewed, this conflict is noted along with the member's name. The member(s) with conflicts are asked to leave the room and are designated in the minutes as having been recused from study deliberations and votings.

Attendance

Attendance Details:

Meeting Chaired by [redacted]

IRB members in attendance:

[redacted]

IRB Members absent:

[redacted]

Non-Members in attendance:

[redacted]

A. Post-Approval Reports

F1.
ID: *IRB#15-000910-PAR-00000009*
Title: *Protocol Incident - Stress and Injury Due to Weekly Peripheral IV Placement*
Principal Investigator: [redacted]

Committee Member Conflict of Interest: [redacted]

Committee Discussion and/or Recommendations:
The Board discussed the subject complaint and proposed procedure to allow for venous catheter placement (Port-A-Cath) as an alternative for the currently approved procedures and acknowledged the FDA's assessment of the procedure, outlined in the November 6, 2015 letter to the Sponsor. Additional clarification from the PI that use of a Port-A-Cath would only be considered in subjects where standard IV placement is problematic, defined by either a subject requiring three or more attempts at venipuncture access at two consecutive visits or five or more attempts at any one visit was provided to the Board and considered with the submission.

The two members with the most direct experience with the use of the Port-A-Cath provided a detailed description of the procedures used during Port-A-Cath placement at UCLA to provide sufficient context for all members. The Board discussed the potential risks and discomforts some subjects currently experience in which they may experience multiple attempts at IV placement each week during a 96 week trial. During this discussion the Board indicated that the potential weekly trauma and undue psychological risks shifts the risk/benefit ratio during the progression of the study, noting that participants are subjected to increased risks and potential removal from the trial.

The Chair provided additional anecdotal information based on conversations with the PI regarding one mother who was so concerned about her son's discomfort that she wished to go outside the trial to have a Port-A-Cath placed. Members then discussed established literature regarding difficult

intra venous access (DIVA) for the intended population and emphasized the psychological risks and trauma experienced in children who are apt to spend increasing portions of their lives receiving intensive medical treatments.

One member cited additional literature regarding risks associated with Port-A-Cath placement, including infection rates, thrombosis, and post-operative complications and members asked about whether the placement of the Port-A-Cath would require changes during the maturation of the participant during the study. Members knowledgeable with clinical Standard Operating Procedures (SOPs) for Port-A-Cath placement occurring at UCLA indicated that the incidence of these risks is rare and that one placement during the course of the study would be sufficient. Additionally, the Board indicated that the risks of infections are minimized in the proposed procedures, as the only administration will occur at the Clinical Translational Research Center (CTRC) by qualified medical staff who will monitor and assess the site at each weekly visit. However, the Board indicated that additional safeguards should be included in the protocol to train the parents to monitor signs of infection during the course of the study. The Board acknowledges the potential risks associated with the Port-A-Cath placement, including risks of infection, general anesthesia, and removal which would need to be included in a revised protocol and consent document.

The Board discussed potential alternatives such as placement of a PICC line and indicated this alternative mode of administration is associated with increased risk of clotting and is more likely to be dislodged or removed by the participant.

The Board determined that the plans for the Port-A-Cath use with additional guidelines provided by the PI are acceptable to the IRB but for the FDA prohibition and that the clinical investigation with the proposed Port-A-Cath use present a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children and therefore proposed to refer the study for special consideration to the FDA under 21 CFR 50.54.

IRB Requests:
8.2 - Evaluation: Study Participant Complaint, Reportable Protocol Violation, Incident, or Deviation from the Approved Protocol to Prevent Immediate Hazards

The Board acknowledges the receipt of the Post Approval Report (PAR) requesting proposed use of venous catheter placement. Given the FDA's assessment of the procedures outlined in the November 06, 2015 letter to the Sponsor, which indicates that the proposed procedure of venous catheter placement is more than a minor increase over minimal risk without the prospect of direct benefit, the Board reviewed the proposed procedures and found that the clinical Investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children. Therefore, the Board has determined that the proposed investigation should be referred for FDA review under 21 CFR 50.54.

Please submit an amendment to include any finalized procedures to the protocol once the FDA review process has concluded or provide additional information to this PAR regarding the status of the subjects for whom the proposed procedures are requested should there be any further developments.

Motion: Acknowledge Receipt - Amendment Required
Vote: For: 13 **Against:** 0 **Abstain:** 0
Conflict of Interest Recused: 0 **COI Name(s):** N.A.
Out of Room:0 **Out of Room Name(s):** N.A.