ORLANDO HEALTH®

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Type of Policy:	***PROTECTION OF HUMAN RESEARCH PARTICIPANTS***	Category:	**Orlando Health Institutional Review Board (IRB)**

Title:	***Reporting Serious Adverse Events***	Policy #:	**0330-1000**
		Replaced #:	ORMC IRB# 6000-0019 MDACCO IRB# 1000-0001-S
Page 1 of 2		Issued By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	**7/19/95**	Approved By:	**SIGNATURE ON FILE** Philip Giordano, MD Institutional Official
Revision Dates:	1/1/01, 3/20/02, 11/12/07, 2/4/08, 1/1/09, 11/23/09, 7/29/11, 9/10/12, 8/14/14, 4/4/17, 4/21/20, 1/18/23, 07/15/25		

I. PURPOSE:

To maintain ethical and legal standards when reviewing adverse events.

II. DEFINITIONS:

Please refer to the IRB Definition Policy added \

III. POLICY:

Investigators will notify the IRB of all serious adverse events that occur at this institution and indicate their recommendations for the continuation, modification, or termination of studies involving the trial agent and/or research intervention. All unanticipated adverse events must be reported to the IRB within the required time frame described in this policy.

IV. PROCEDURE:

A. Reporting Local Serious Adverse Events:

1. **Prompt reporting:** All serious, unexpected, local adverse events definitely or possibly related to a trial agent must be promptly reported on the current Serious Adverse Event Report form to the IRB **within 5 working days** after site awareness. In addition, this type of event should be reported to the sponsor who will inform the Food Drug Administration (FDA), Office for Human Research Protections (OHRP) and/or National Institute of Health (NIH).
    i. Since it is unnecessary to include Protected Health Information, all patient information submitted regarding the adverse event must be de-identified on the IRB form. This is in accordance with HIPAA Guidelines' Minimum Necessary Standard.
    ii. Unanticipated risk may indicate that modifications to the investigational plan (which may also include changes to the informed consent form and/or plan to notify or re-consent enrolled subjects [participants]) are needed for the adequate protection of research subjects (participants). These modifications may be submitted with the IRB form.
    iii. Upon review, the IRB will acknowledge the submission of the SAE. The IRB has the authority to recommend modifications to an approved study, suspend enrollment, or terminate the study in order to increase the protection of human subjects (participants).
2. **At the time of Continuing Review:** All local serious adverse events that met or did not meet the prompt reporting criteria during the review period must be reported at the time of Continuing Review, using the Internal Serious Adverse Event Log Sheet.

B. Reporting External Safety Reports: The Office for Human Research Protection (OHRP) notes that reports of individual external adverse events often lack sufficient information to allow investigators or IRBs to make meaningful judgments about whether the adverse events are unexpected, related or possibly related. Individual adverse events

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should only be reported to the Orlando Health IRBs when a determination has been made that the events meet the criteria for an unanticipated problem. Ideally, external adverse events occurring in subjects (participants) enrolled in a multicenter study should be submitted for review and analysis to a monitoring entity (such as the research sponsor, DSMB/DMC, or statistical center) in accordance with a monitoring plan described in the IRB-approved protocol.

A. External Safety Reports do not need to be reported to the IRB unless they require a change to the protocol risks, the Investigator Brochure, the Informed Consent Form, or a change in the conduct of the study (e.g. temporary hold to enrollment). The changed documents should be uploaded with the Safety Report(s) on the Research Related IND Safety Report (External) Serious Adverse Event Line Listing form.

1. Only external adverse events that are identified by the sponsor in their report must be reported promptly to the IRB on the appropriate IRB form as an unanticipated problem under HHS regulation 45 CFR 46.103(b)(5). These reports should include both:
    i. a clear explanation of why the adverse event or series of adverse events has been determined to be an unanticipated problem; and
    ii. a description of any proposed changes to the investigational plan or other corrective actions to be taken by the investigators in response to the unanticipated problem.

V. DOCUMENTATION:

B. Serious Adverse Event Report Form
C. Internal Serious Adverse Event Log Sheet (Continuing Review)
D. Research Related IND Safety Report (External) Serious Adverse Event Line Listing form

VI. REFERENCES:

A. Office for Human Research Protection (OHRP) Guidance on Reviewing and Reporting Unanticipated Problems, January 15, 2007
B. Department of Health and Human Services (HHS) regulations 45 CFR part 46.103(b)(5)
C. IRBNet Template Library