

 **INSTITUTIONAL REVIEW BOARD**

***REPORT OF HUMAN VOLUNTEER INJURIES AND/OR SERIOUS-UNFORESEEN COMPLICATIONS***

The University of Detroit Mercy's Institutional Review Board (IRB) requires that the following report be completed and submitted within 48 hours of the occurrence of any human volunteer injuries and/or serious-unforeseen complications. The form should be returned to:

**Institutional Review Board**

**Academic Affairs Fisher Bldg., 5th Floor Voice: (313) 494-6634**

**Email:** **wheatemi@udmercy.edu**

Title of Project:

IRB Protocol #:

Last Approval Date:

Volunteer's Name:  Age:

Date of Incident:  Hospitalization?

Please explain type of injury and reason for incident:

Did the incident result in death?

Was the incident a direct result of the research?

If an experimental drug/device was involved, please provide name/number:

Has the FDA been notified?

If yes, please attach FDA form 1369 and/or related correspondence.

Signature

Principal Investigator Date