

**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 to the Office for Sponsored Projects and Research Administration *within 48 hours of the occurrence* of any human volunteer injuries and/or serious-unforeseen complications. The form should be returned to:

**Office for Sponsored Projects and Research Administration
Engineering Building, E259
McNichols Campus
Tel: 313/993-1587**

(Please Type)

TITLE OF PROJECT: _____

IRB PROTOCOL #: _____ LAST APPROVAL DATE: _____

VOLUNTEER' S NAME: _____ AGE: _____

DATE OF INCIDENT: _____ HOSPITALIZATION? YES ___ NO ___

PLEASE EXPLAIN TYPE OF INJURY AND REASON FOR INCIDENT (USE BACK OF THIS FORM AND ADDITIONAL SHEETS IF NEEDED):

DID INCIDENT RESULT IN DEATH? YES ___ NO ___

WAS THE INCIDENT A DIRECT RESULT OF THE RESEARCH? YES ___ NO ___

IF AN EXPERIMENTAL DRUG/DEVICE WAS INVOLVED, PLEASE PROVIDE NAME/NUMBER: _____

HAS THE FDA BEEN NOTIFIED? YES ___ NO ___
IF YES, PLEASE ATTACH FDA FORM 1369 AND/OR RELATED CORRESPONDENCE.

PRINCIPAL INVESTIGATOR SIGNATURE DATE