



6940 Columbia Gateway Drive | Suite 110 | Columbia MD 21046
410-884-2900
www.biosafetycorp.com | clientservices@biosafetycorp.com

SUBMISSION FORM IBC D: INCIDENT REPORT

Date:
Protocol ID:
Site Name:

I. INCIDENT DESCRIPTION

1.	Please describe what happened, what evaluations or remedies were undertaken as well as any and all outcomes.		
2.	Should changes be made to the protocol procedures? If yes, please describe:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3.	Should changes be made to your site's SOPs? If yes, please describe:	<input type="checkbox"/>	<input type="checkbox"/>

II. SERIOUSNESS OF INCIDENT

4.	Please check all that apply: <input type="checkbox"/> Non-serious <input type="checkbox"/> Hospitalization <input type="checkbox"/> Other (describe):	<input type="checkbox"/> Life threatening <input type="checkbox"/> Disability/incapacitation	<input type="checkbox"/> Death
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III. NOTIFICATION

Yes	Date	Explanation
<input type="checkbox"/> NIH OBA		
<input type="checkbox"/> Public Health Department		
<input type="checkbox"/> Sponsor		
<input type="checkbox"/> Institutional Official		

IV. CORRECTIVE ACTION PLAN

6.	Describe steps taken/to be taken to prevent this type of incident in the future:
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