UNCG UNANTICIPATED PROBLEM/ADVERSE EVENT FORM

Institutional Review Board

2718 MHRA

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|  |  |
| --- | --- |
| Date received ORI | Acknowledged by |
|  |  |

 Check one Check one

|  |  |
| --- | --- |
| [ ]  Adverse Event [ ]  Unanticipated Problem Report[ ]  Unintentional Deviation From Approved Protocol  | [ ]  Initial Report[ ]  Follow-up Report |

|  |  |
| --- | --- |
| NAME OF AGENCY | PROTOCOL NUMBER |
|       |       |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Name | Department | Phone and e-mail |
|  UNCG  Investigator |       |       |       |
|  Submitted by |       |       |       |
| Agency Contact |       |       |       |

ASSOCIATED RISK ISSUES TYPE OF STUDY

|  |  |  |
| --- | --- | --- |
| [ ]  Legal[ ]  Financial[ ]  Privacy[ ]  Other | [ ]  Breach of Confidentially[ ]  Social | [ ]  Survey [ ]  Other[ ]  Intervention[ ]  Evaluation[ ]  Observation |

DATES

|  |  |  |  |
| --- | --- | --- | --- |
| Event      | PI First Notice      | Notification Funding Agency      | Report to ORI      |

SUBJECT \*= mandatory

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name | Number\* | Gender\* | Age | Indication of concern |
|       |       |       |       |       |

Describe the event

|  |
| --- |
|       |
|       |

EVENT EVALUATION

|  |  |  |
| --- | --- | --- |
| Expectedness | Severity | Correlation to Study |
| [ ]  Anticipated[ ]  Unanticipated | [ ]  Very serious[ ]  Somewhat serious[ ]  Minimally serious[ ]  Not serious | [ ]  Definitely[ ]  Probably[ ]  Possibly[ ]  Probably Not[ ]  Definitely Not |

What is the frequency of this problem?

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|       |

Was there information in the consent form that addressed this issue? If so what?

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|       |

Should the consent form be modified or should a consent addendum be issued?

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Key words describing the event

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|       |

What was the impact on the participant?

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|       |

How was this event resolved? What was the corrective action?

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|       |

SIGNATURES

|  |  |  |
| --- | --- | --- |
|  | Prepared | Investigator |
| Signature |  |  |
| Printed  |       |       |
| Date |       |       |

ACTION TAKEN BY ORI

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| --- |
|  |

Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_