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

|  |
| --- |
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|  |

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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| --- |
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Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_