LIBERTY IRB, Inc.
A CENTRAL INDEPENDENT REVIEW BOARD

Full Accreditation

REPORTING FORM

Liberty IRB Tracking #	
Protocol Number and Version Date:	
Title of Study:	
Principal Investigator Name:	
Subject ID:	
Type of Report: ☐ Initial ☐ Follow Up	
Date of Event:	Date Investigator became aware of Event:
Dates of study treatment: From _____	To: _____

NOTE: Reporting Form Requirements are on last page of this form.

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Investigators will be required to promptly report, within 5 business days of becoming aware, to the IRB any changes in the research activity and the problems listed below. Mark the box that corresponds to the problem being reported.

Criteria	Yes	No
1. Internal adverse events which are unexpected (unanticipated) and related to the research. Internal adverse events are those adverse events experienced by subjects enrolled by the investigator at that institution. In the context of a single center clinical trial, all adverse events would be considered internal adverse events. * In this instance, a *local investigator typically becomes aware of the event from their subject, another collaborating local investigator, or their subject's health care provider.*		
2. External adverse events which are unanticipated problems involving risks to participants and others, as determined by the study investigator. *These events are experienced by subjects enrolled by investigators at other institutions engaged in the clinical trial.* **Only when a particular adverse event or series of adverse events is determined to meet the criteria for an unanticipated problem should it be submitted to the IRB.*		
3. Changes made to the research without prior IRB approval in order to eliminate apparent immediate harm.		
4. Other unanticipated information that indicates participants or others might be at increased risk of harm such as a new risk, identified in an interim safety analysis, revised package insert, revised investigator brochure, publication in the literature or a DSMB report.		
5. Unanticipated problems involving risks to participants or others will be defined as any report of information that is (1) unanticipated and (2) indicates that participants or others are at increased risk of harm. Examples – see last page of this form.		
6. Allegation or finding of non-compliance. This is allegation or finding of non-compliance by the principal investigator and/or staff. **This instance of non-compliance is not when the subject does not follow procedure.*		

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7. Major protocol deviations or violations that might affect the rights safety and/or welfare of subjects (i.e., changes made to research without IRB and sponsor approval).		
8. Unanticipated adverse device effects (Any serious adverse effect on health safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application) or any other unanticipated serious problem associated with a device that relates to the rights safety, or welfare of subjects.)		
9. Other event required by Sponsor, CRO, Monitor, or Auditor to be reported.		
10**.** Describe the adverse event, unanticipated problem, deviation, or non-compliance that occurred. Provide relevant subject history, concomitant treatments or any other contributing factors. * ***Attach further explanation if necessary.***		
11. Was the event considered to be related to the study drug/study device? ***Attach further explanation if necessary.***	Yes	No
12. Did the event result in harm to the subject? ***Attach further explanation if necessary.***	Yes	No

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13. Describe the actions taken in response to this event. If these included changes to the research without IRB approval, describe the changes. * ***Attach the changes for review.***		
14. Did these actions alleviate the problem?	Yes	No
15. If the problem is still unresolved what further action will be taken?		
16. Did Subject continue participation in the study?	Yes	No
17. Has the sponsor been notified of these events, including whether or not subject continued in the study? ***If no, indicate why.***	Yes	No
18. Has the appropriate regulatory agency been notified? * ***If yes, indicate the agency notified.*** ☐ FDA ☐ OHRP ☐ Other: _____	Yes N/A	No
19. If the reporting is one of non-compliance was the PI the one that disclosed the event?	☐ Yes	☐ No

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20. If #19 is no, state who alleged the non-compliance.
21. If not reported within 5 business days, please explain lapse.

Name of Person Completing Form (contact person for questions)	
Name:	
Title:	
Phone Number:	
Fax Number:	
Email Address:	
Signature of person completing form:	
Date:	Signature:

Principal Investigator Signature *(required):*	
Date:	Signature:

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Reporting Form Requirements

Investigators will be required to promptly report, within 5 business days of becoming aware, to the IRB any changes in the research activity and the problems listed below:

- **Internal adverse events which are unexpected and related to the research;**
- **External adverse events which are unanticipated problems involving risks to participants and others, as determined by the study investigator;**
- **Changes made to the research without prior IRB approval in order to eliminate apparent immediate harm;**
- **Other unanticipated information that indicates participants or others might be at increased risk of harm such as a new risk, identified in an interim safety analysis, revised package insert, revised investigator brochure, publication in the literature or a DSMB report.**
- **Unanticipated problems involving risks to participants or others will be defined as any report of information that is (1) unanticipated and (2) indicates that participants or others are at increased risk of harm.**
- **Allegation or finding of non-compliance;**
- **Major protocol deviations or violations that might affect the rights safety and welfare of subjects;**
- **Unanticipated adverse device effects (Any serious adverse effect on health safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application) or any other unanticipated serious problem associated with a device that relates to the rights safety, or welfare of subjects.)**

Examples of Unanticipated Problems (#5 on page 1):

- An investigator collects individually identifiable information and stores them on a laptop computer without encryption. The computer is stolen. This was a) unexpected; b) related to participation in the research; and c) placed the subjects at a greater risk of psychological and social harm than was previously known or recognized.
- As a result of a processing error, a subject in a multi-center trial receives a dose of study drug 10 times higher than dictated by the protocol. While the subject experienced no detectable harm or adverse effect, this constitutes an unanticipated problem for the institution where the dosing error occurred.
- Subjects with cancer are enrolled in a clinical trial evaluating an investigational biologic product derived from human sera. After several subjects received the product a study audit reveals it was obtained from donors not appropriately screened and tested for viral contaminants. . This was a) unexpected; b) related to participation in the research; and c) placed the subjects at a greater risk.

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NOTE – these examples were taken from Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects – www.hhs.gov/OHRP/policy