Cecil College: IRB Adverse Event Form

Submit one electronic copy to irb@cecil.edu (PDF or .doc file) within 24 hours of the research team's awareness of the event.

The Cecil College IRB reviews all adverse events during research involving human subjects. Please see the HHS.gov website for more information on adverse events https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#Q2.

Principal investigators should monitor their research for any potential adverse events. If an adverse event occurs (either Category A or B), this form must be submitted to the IRB within 24 hours of awareness of the event. The IRB requires that the event be reported even if it does not seem to be connected to the research project. No data collection may take place until the Adverse Event Form is reviewed by the IRB and the PI has received documentation of how to proceed.

Category A: Serious Adverse Event

- A serious adverse event occurs within 48 hours of participation in research, and
- incorporates a serious adverse event (death, a life-threatening experience, hospitalization, or extended hospitalization, persistent or significant disability or capacity, congenital anomaly or birth defect).

Category B: Other Unanticipated Event Adversely Effecting Subjects or Others

All three of the following statements are true

- Event has caused harm to the subject, has impacted the subject detrimentally, has worsened the result of their participation, or has resulted in increased risk to the subjects or others (even if the risk has not resulted in harm).

  Examples: Misplacing a subject's record, mild distress after completing the research, etc.
- Event or outcomes were not described or disclosed as a risk for participation in the research, or they have occurred with increased frequency after completing the research.
- Event or outcomes were possibly, probably, or definitely linked to the research.

Part I: Research Staff

Date of submission:	
Principal Investigator Name (This must be full time faculty/approved staff):	
Email:	Phone:
Department/Division:	
If this submission involves another faculty member, a student, or an outside entity functioning as a Co-Investigator (Co-I), please complete the following information. Co-I Name: Co-I Email: Co-I Phone: Co-I Affiliation (Cecil College, Other Institution, Outside Entity):	

Part II: Adverse Event Timing, Location, and Type

Date of event(s)
Date when research team or PI was notified/aware of event(s):
Type of adverse event: Category A—Serious Adverse Event Category B—Other Unanticipated Event Adversely Affecting Subject or Others
Provide a description of the event here including the event, the location in which the research participation occurred, the location of the adverse event, the people present during the research participation, and the people present during the adverse event or when the adverse event was discovered.
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Describe any steps taken by the research team in response to the event in an attempt to resolve the issue.

Indicate the subject's current participation level in the research:

- stopped research participation.
- withdrew from further participation.
- withdrawn by principal investigator from further participation.
- was completed.
- is actively continuing.
- is continuing with follow-up only.
- Other: Explain:

Yes	No	Did this event cause?
		Psychological harm or injury.
		Physical harm or injury.
		Congenital anomaly/birth defect
		Economic harm
		Breach of confidentiality
		Increased risk of psychological, social or economic harm or injury
		Increased breach of confidentiality
		A life-threatening experience
		Transport to a medical facility
		Hospitalization
		Prolonged a hospital stay
		Death
		Other, explain:
Yes	No	If death occurred was it:
		Related to research
		Related to a study drug
		Related to a study device
		Other, explain:

Part III: Subjects

Provide the subject ID of the individual(s) who experienced the adverse event
Provide the subject(s)' age.
Does the subject identify with or belong to any federally protected class? Yes or No If "Yes", please specifiy.

Describe any pre-existing conditions of the subject(s)

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Yes	No	Unsure	
			Has any previous research produced this type of event? If "Yes", please describe previous research results.
		Unsure is not an option	Was the event related to the risks as presented in the research proposal and/or consent documents? If "Yes", include a copy of the proposal and consent document with relevant sections highlighted.
		Unsure is not an option	Does the PI feel that the research project or consent form need revision? If "Yes", please submit all revised materials with the appropriate Change Form.
		Unsure is not an option	Has any previous research produced this type of event? If "Yes", please describe previous research results.

Expected	Unexpected	
		In the PI's judgement was the event expected or unexpected?
Serious	Not serious	
		In the PI's judgement was the event serious or not serious?

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□□
□ □
In the PI's judgment, was there a relationship between the event and the research? • □ Definitely: clearly related to the research • □ Probably: likely related to the research • □ Possibly: may be related to the research but not enough information is available to assess this • □ Probably not: doubtfully related to the research • □ Definitely not: clearly not related to the research
□□

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Does the PI feel that other research subjects should be notified?

- ☐ New subjects
- ☐ Currently enrolled subjects
- ☐ Subjects that have completed the research
- ☐ None

If any of the above (other than "none") are marked, the PI must submit a Change form with revised consent forms attached.

Does the PI feel that research should:

- ☐ Continue as planned with no changes to the research project or consent process.
- ☐ Continue with changes to the research project or consent process, as previously noted on this form.
- ☐ Suspend new subject enrollment until the event is assessed further.
- ☐ Be terminated (stopped completely), with all subjects removed from research.

- Have any of the following organizations or regulatory bodies been notified of the event: ☐ Research sponsor/coordinating site/other IRB
- ☐ Other (like funding source)

Part V: Adverse Event in Relation to Research