**Colorado College IRB Adverse Event Report Form for Approved Projects**

You must fill out this form when a participant in your IRB-approved research has suffered an adverse (harmful) event or outcome following participation in your research. There are two relevant categories of adverse events/outcomes, the first of which is more likely given the type of research generally carried out at Colorado College.

Category A: Any event/outcome for which all three of the following are true:

1. An event or outcome has occurred in relation to your research that has

* resulted in harm to one or more participants, and/or
* affected one or more participants detrimentally, and/or
* worsened an already harmful condition or situation as a result of their participation, and/or
* resulted in increased risk of harm to the participant or to others (whether or not the risk has actually resulted in harm)

2. The consent process/form did not describe this event or outcome as a risk of participation in the research OR, though described as a risk, the event or outcome has occurred with unexpected severity or frequency.

3. The event or outcome was definitely related to participation in the research OR it is reasonable to conclude that the event or outcome was related to participation. “Reasonable” in this case means that a reasonable person with access to all of the information about the research project and about the adverse event or outcome would likely or definitely conclude that the event or outcome occurred as a result of participation in the research.

Category B: Any serious adverse event/outcome that occurs within 48 hours of participation in the research. Serious adverse events/outcomes are those resulting in death, a life-threatening experience, hospitalization or prolongation of existing hospitalization, or a persistent or significant disability or capacity limitation. Every serious adverse event or outcome occurring within 48 hours of participation within research of which the researcher becomes aware must be reported to the Colorado College IRB on this form even if the event/outcome may not be associated with participation in research.

This form is a Word document, meaning that you can add or delete space as necessary. Email this form to the IRB chair (audiskessler@coloradocollege.edu) within 24 hours of learning of the adverse effect or outcome.

Name:

Title of research project:

Email address: Phone number:

Faculty advisor if relevant:

A. Information about Adverse Event/Outcome

1. Date of adverse event/outcome:

2. Date of adverse event/outcome’s discovery by researcher:

3. Date of this report:

4. Where was the research activity conducted?

5. Where did the adverse event/outcome take place?

6. Who was present when the adverse event/outcome was discovered?

7 Which of the two categories on page 1 best describes the adverse event/outcome?

\_\_\_\_\_ Category A \_\_\_\_\_ Category B

B. Information about the Participant(s) Experiencing the Adverse Event/Outcome

1. Participant name(s):

2. Participant age(s):

3. Any other relevant information about participant(s), such as pre-existing medical or psychological conditions:

C. Description of Adverse Event/Outcome

1. Please check all that apply. This event:

\_\_ caused psychological/emotional harm or injury

\_\_ caused physical harm or injury

\_\_caused social harm or injury

\_\_ caused political harm or injury

\_\_ caused academic harm or injury

\_\_ caused legal harm or injury

\_\_ caused criminal harm or injury

\_\_ caused academic harm or injury

\_\_ caused financial harm or injury

\_\_ caused a breach of confidentiality

\_\_ increased risk of psychological, social, or any other type of harm to participant

\_\_ increased the risk of a breach of confidentiality

\_\_ was a life-threatening experience

\_\_ required emergency treatment

\_\_ required hospitalization

1. Please check all that apply. This event (cont.):

\_\_ Prolonged a current hospital stay

\_\_ Involved the death of a participant

\_\_ Other

2. Provide a narrative description of the event or outcome:

D. Resolution

1. Describe any/all steps and actions taken in response to the event/outcome:

E. Participant Status

1. What was the participant’s situation in relation to the research after the adverse event/outcome? Check only one answer.

\_\_ Participant stopped research participation and/or withdrew from further participation

\_\_ Researcher withdrew participant from further participation

\_\_ Participant had already completed research

\_\_ Participant continued research participation

\_\_ Other (please describe)

2. Describe the participant’s prognosis with regard to recovery.

F. Event Categorization

1. The event/outcome is \_\_\_\_\_ expected \_\_\_\_ not expected

2. The event/outcome is \_\_\_\_\_ serious \_\_\_\_ not serious

3. In your judgment as researcher, was there a relationship between the event/outcome 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 determine

\_\_\_ Probably not; doubtful that the event/outcome is related to the research

\_\_\_ Definitely not; clearly not related to the research

G. Relation to Risks

1. In your judgment, was this event or outcome related to the risks as presented in the consent process or research protocol?

\_\_\_ Yes \_\_\_ No

2. If yes, attach a copy of the consent document(s) and/or research protocol with relevant sections highlighted. (Answer this question regardless of your answer to #1 immediately above.)

\_\_\_ I answered question #1 immediately above “yes” and have attached the consent document(s) and/or research protocol as requested

\_\_\_ I answered question #1 immediately above “no” and have not attached documents/protocol

H. Revisions

1. Based on your knowledge of this adverse event/outcome, are you revising the consent document(s) and/or research protocol?

\_\_\_\_ Yes \_\_\_\_ No \_\_\_\_ Unsure and would welcome guidance

2. Please check one of the below options based on your answer to #1 immediately above.

\_\_\_ I answered “yes,” and have attached the revised consent document(s)/protocol

\_\_\_ I answered “no,” and have not attached any documents

\_\_\_ I answered “unsure,” and will contact the IRB chair separately to ask for guidance

I. Notification of Participants and Others

1. Who do you think should be notified of this adverse event/outcome? Please check all that apply.

\_\_\_ New participants

\_\_\_ Current participants

\_\_\_ Participants who have completed the research

\_\_\_ Parents/guardians/legally authorized representatives (leave blank if not relevant)

\_\_\_ No one

2. Please check one of the below options based on your answer to #1 immediately above.

\_\_\_ I answered “no one,” and have not attached a notification letter

\_\_\_ I checked an answer other than “no one” above, and have attached one or more notification letters as appropriate to the stakeholders I selected

3. In your judgment, do you need to undergo a new consent/assent process with those who have already consented/assented to participate in your research?

\_\_\_\_ Yes \_\_\_\_ No \_\_\_\_ Unsure and would welcome guidance

(continued)

4. Please check one of the below options based on your answer to #1 immediately above.

\_\_\_ I answered “yes,” and have attached the revised consent/assent/parent/guardian permission document(s) as appropriate

\_\_ I answered “no,” and have not attached any documents

\_\_ I answered “unsure,” and will contact the IRB chair separately to ask for guidance

J. Implications for Research

1. Given the adverse event/outcome, which of the below best represents your judgment about continuing the research at this time? Check only one option.

\_\_\_ The research should continue as planned with no changes to the research protocol or consent process

\_\_\_ The research should continue but with changes to the protocol or consent process

\_\_\_ I am suspending new participant enrollment until I can further evaluate the event/outcome

\_\_\_ I am terminating the research project at this time, removing all participants from research, and destroying all of their research-related information

K. Reports Filed

1. Have you reported the adverse event/outcome to any other people, organizations, or regulatory bodies?

\_\_\_\_ Yes \_\_\_\_ Not yet but I plan to do so soon \_\_\_\_\_ No

2. If you answered “yes” or “not yet” immediately above, list any individuals, organizations, or regulatory bodies to whom/which you have reported or will report the event/outcome.

3. If you answered “yes” or “not yet” to question #1 in this section, check one of the following:

\_\_\_ I have attached any reports going to others with this document

\_\_\_ I will forward any relevant reports to the CC IRB as soon as possible

L. Researcher Assurances

1. I have reviewed the contents of this form, with attachments, and I certify that the information provided is complete and accurate to the best of my knowledge.

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Researcher signature (electronic signature is acceptable) Date