

Chaminade University Institutional Review Board

Form V

Adverse or Unanticipated Event Report Form

Background Information:

1. Timeline for Reporting of Adverse Events

Using the Adverse Event Report Form (Form V), PIs are required to report to the IRB **serious and related events** no later than 2 working days after discovery of their occurrence. Events that are not serious and are not related to study procedures may be reported with the Form IV Annual Report. All other events must be reported within 5 working days after discovery of their occurrence. This policy applies to events that occur at CUH or at an off-campus study site.

2. Background and Importance

DHHS and FDA regulations require prompt reporting to the IRB, and appropriate federal departments or agency heads, of 1) unanticipated problems involving risk to participants or others, 2) any serious or continuing noncompliance with regulations or the requirements of the IRB, and 3) any suspension or terminations of IRB approval.

It is the responsibility of the PI to assess events that occur during the course of a research protocol, and determine which of the following descriptions apply. The IRB will review reports and make a final determination, indicating agreement or disagreement with the PI's assessment, and why.

3. Adverse Events

An **Adverse Event** is an event that occurs during the course of a research protocol that either causes physical or psychological harm, or increases the risk of physical or psychological harm, or results in a loss of privacy and/or confidentiality to a research participant or others (such as family members).

An **Anticipated Adverse Event** is one that is reasonably expected and listed in the protocol and consent form as a risk of participating in the research. Examples of an anticipated adverse event include, but are not limited to, the following:

- A participant in an exercise physiology study experiences muscle strain following an exercise session;
- A participant in a study with blood draws experiences light headedness or fainting during the blood drawing process;
- A participant in a study of post-traumatic stress syndrome becomes upset during the re-telling of the traumatic event and requires a referral to a counselor.

An **Unanticipated Adverse Event** is one that was not reasonably expected and/or is not listed in the protocol and consent form as a risk of participating in the research. Examples of an unanticipated adverse event include, but are not limited to, the following:

- A participant in a study of the benefits of eating strawberries experiences a previously undetected allergy to strawberries;
- A child participant in a study of how to improve classroom behavior experiences bullying by other students as a result of her participation in the study.

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A **Serious** adverse event is one whose magnitude or frequency is above expectation. For example:

- Previous research data indicates that the expected rate of an injury from a certain interventional procedure is 1 in 1000, but the same procedure used in a protocol under review has a much higher rate (e.g., 1 in 100);
- An anticipated side effect of a certain dietary protocol results in a much more serious manifestation of that effect than would be expected (i.e., a high-fiber diet results in severe diarrhea and vomiting requiring hospitalization).

A **Related** adverse event is one that, in the opinion of the investigator, is likely caused by or affects the research. For example:

- A participant in a study about post-traumatic stress disorder experiences a panic attack after telling the investigator about a incidence of childhood sexual abuse;
- A participant in a study about the benefits of a nutritional supplement on recovery from weight lifting experiences an allergic reaction to the product after it is ingested.

Events that are not serious and are not related to study procedures should be reported with the Annual Report (Form IV) Examples of unrelated events that may be reported at the time of re-approval include:

- A participant in a study gets the flu and has to withdraw from the study (report as a withdrawal);
- A participant in a longitudinal study of high school students' transition to college life drops out of school and withdraws from the study (report as a withdrawal);
- A participant in an observational study of child behavior during recess falls on the playground and sprains her ankle (report in summary of findings);
- A participant in a study on the benefits of eating carrots on eyesight reports an incident of food poisoning from eating out at a restaurant and has to miss one of six scheduled visits to the laboratory. The protocol should accommodate for missed session make-ups. If not, this would be reported as a protocol deviation (missed session) but not as an adverse event (food poisoning unrelated to study procedures).

Examples of **serious and related** adverse events are:

- The death of a research participant due to research procedure(s);
- Any change to the protocol made without prior IRB review to eliminate apparent immediate hazard to a research participant or others;
- Any event that requires prompt reporting according to the protocol or the study sponsor;
- A serious breach of privacy or confidentiality of research participants or others (such as family members);
- Any publication in the literature, safety monitoring report, interim result, or other finding that indicates an unexpected change to the risks or potential benefits of the research;
- Any complaint of a participant that indicates an unanticipated risk or which cannot be resolved by the research staff;
- Any other event or other problem which, in the opinion of the PI, was (1) previously unforeseen and (2) presents risks to research participants or others.

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4. Unanticipated Problems, Protocol Deviations and Noncompliance

An **Unanticipated Problem** is defined as any unforeseen event that involves risk to the participant or others that is related to either a research intervention or interaction, or the conduct of the study in general. Examples of unanticipated problems involving risk include, but are not limited to, the following:

- an accidental or unintentional change to the IRB-approved protocol (e.g., the software program for an on-line survey study about college students' use of illegal drugs has a glitch that enables research participants to view other participants' identifiable survey responses);
- a complaint from a participant that indicates an unanticipated risk (e.g., loss of employment due to disclosure of data, etc.);
- unexpected changes to the risk/benefit profile of the study (e.g., based on literature, safety reports, interim results or other findings);
- unforeseen events involving the research team (e.g., the loss of a laptop computer with identifiable participant information, sudden unavailability of the PI and/or co-investigator, etc.);
- unexpected serious adverse events (internal or external) that in the opinion of the PI may be related to the study intervention;
- any change to the protocol taken without prior IRB review to eliminate apparent immediate hazard to a research participant when the immediate hazard is, in the opinion of the PI, related to the study.

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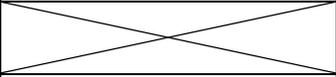
Adverse or Unanticipated Event Report Form

Date of Report: _____

Protocol #: _____

Protocol Title: _____

PI, Student Investigator, Correspondent Information:

	Principal Investigator (PI)	Student Investigator (only for Student Initiated Research)	Correspondent (primary point of contact for correspondence, if applicable)
Name (First, Last, Degree):			
Department:			
Mailing Address:			
Preferred Phone #:			
Emergency Phone #			
Preferred E-Mail Address:			

Type of Report (place an "X" next to the appropriate type):

Initial Report

Follow-up Report (If this is a follow-up, please use the original report and add new text in the follow-up section.)

Explain the following (provide response in the second column):	
Date of event/problem:	
Date event/problem was discovered by research personnel:	
Did the event/problem take place at CUH campus? Specify yes/no. If yes, provide the specific location.	
If not, specify the off-campus site where the event took place:	
Participant ID # (do not provide personal identifiers):	
Participant's Gender:	
Participant's Age:	

Please Note: Events that are not serious and are not related to study procedures may be reported at the time Annual Report preparation (Form IV).

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Describe Adverse or Unanticipated Event/Problem - In the space below the text box, provide a succinct description of the adverse event/problem and attach any other pertinent documentation. Indicate if the event caused harm to the participant or others. Include a list of the study personnel who were present during the event and provide the name of the person on the study team to whom the event was reported.

Similar Events/Problems – In the space below the text box, indicate whether there been other reports of similar adverse events to the drug, device, or procedure in this study? Indicate “Yes” or “No.” If yes, please summarize.

Medical Treatment/Referral to Mental Health Professional – In the space below the text box, describe the medical treatment (if any) that was offered/provided to the participant and the participant’s response. Attach a copy of the medical monitor’s report (do not include personal, identifiable information).

Length of Participation – In the space below the text box, describe how far into the protocol had the participant progressed before the adverse event occurred. Be specific (e.g. phase 1, day 3).

Contact with Participant After the Event/Problem – In the space below the text box, describe when the participant was contacted, who contacted the participant, result of the follow-up, etc.

Participant Participation After the Event/Problem – In the space below the text box, describe the following: whether the participant was allowed to continue in the study, continue with follow-up only, participant withdrew, PI withdrew the participant, etc.

Other Entity(ies) Event Has Been Reported To – In the space below the text box, indicate if the event was reported to the study sponsor, FDA, other IRB, etc. Specify the date, contact information (email or phone number) and position of the person contacted.

In the opinion of the Principal Investigator:	Indicate “Yes” or “No”
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Did this event cause harm to the participant or others?	
Was the event unanticipated?	
Was the event serious?	
Was the event related to the research?	
Is this event listed in the protocol?	
Is this event listed in the consent form?	
Is a modification required to the data safety monitoring plan?	
Is a modification required to the protocol?	
Is a modification required to the consent form?	
Is a modification required to other documents?	
Should the study be suspended?	
Should the study be terminated?	

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Prevention of Another Event of this Type – In the space below the text box, describe, if applicable, what plan has been, or will be, implemented to ensure that this type of event will not occur again? Indicate N/A if not applicable. Describe the timeline for implementation of this plan.

Follow-Up Report – In the space below the text box, provide relevant follow-up information such as:

- Final outcome of event
- Attach a copy of Medical Monitor's report (with personal identifiers removed), if applicable
- If any of the follow-up information changes the previously reported information indicate how and why.

Please note that serious and related and unanticipated adverse events require full IRB review, and warrant the suspension of new enrollment pending IRB review.

Original Signature of Principal Investigator	Date