**USMC IRB Unanticipated Problem/Adverse Event Report**

**Immediate Action**: Notify the IRB Chair immediately by telephone or email if the problem or event involves potential or actual harm to subjects, increased risks to subjects, or changes in subjects’ rights.

**USMC IRB Points of Contact**

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| Dr. Kerry Fosher  IRB Chair  Director, Human Research Protection Program  kerry.fosher@usmcu.edu | 571-289-6448 | Ms. Yvette Bethune-Cherry  IRB Administrator  Human Research Protection Program Specialist  yvette.bethune@usmcu.edu | 703-853-6222 |

**References**

The primary reference for research protocols conducted under the oversight of the USMC IRB is the USMC HRPP Policy and Procedures. The policy and other resources are available on the USMC HRPP website (https://www.tecom.marines.mil/Resources/USMC-Human-Research-Protection-Program/).

**Instructions**

* If the problem or event involves potential or actual harm to subjects, increased risks to subjects, or changes in subjects’ rights, this template should be used after a principal investigator (PI) has had an initial conversation with the IRB Chair.
* **Do not include information that could identify subjects in this report or attachments unless directed to do so by the IRB Chair**.
* Enter information in the blank table cells associated with each item. The table cells in each section will expand to allow you to enter as much information as needed.
* Complete all sections as thoroughly as possible to ensure the IRB has the information needed to conduct the review. If necessary, attach additional information.
* In the final section, list all materials you are submitting with the report.
* If you have questions about what to include, reach out to the IRB contacts above.

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| **Protocol Information** | |
| Protocol Number: |  |
| Protocol Title: |  |
| Principal investigator name, command, and contact information: |  |

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| **Unanticipated Problem or Adverse Event** | |
| 1. | Date unanticipated problem or adverse event occurred (if known). |
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| 2. | Date unanticipated problem or adverse event was discovered. |
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| 3. | Summarize the unanticipated problem or adverse event. |
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| 4. | Summarize actions taken to address the unanticipated problem or adverse event. |
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| 5. | Explain the actual or potential impact on subjects or others (include the number of individuals actually or potentially affected). |
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| 6. | Explain how the unanticipated problem or adverse event relates to the research (e.g., directly caused by the research, tangential to the research, an unrelated event). |
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| 7. | Discuss any patterns or trends among all unanticipated problems or adverse events occurring on this project (e.g., have other issues occurred previously and, if so, are they related to the issue you are reporting now). |
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| 8. | What changes do you recommend to the protocol, training of research personnel, or other aspects of the research to address the unanticipated problem or adverse event? |
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| **Attached Materials** |
| NOTE: Use this section to list all materials that will be submitted with the report. Include a brief description of the relevance of the item to the report. Add additional rows if needed. |
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