**USMC IRB Scientific/Scholarly Review Template**

**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 that will be reviewed by 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/).

**Principal Investigator Instructions**

* The principal investigator should provide this template to the scientific reviewer.
* Criteria for selecting an appropriate scientific reviewer are available in the policy above.

**Scientific Reviewer Instructions**

* By submitting this review, you attest that you do not have a conflict of interest.
* 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.
* A brief discussion of each item is more useful to the IRB than yes/no answers.
* If you have no knowledge of a particular aspect of the project or research team or are not qualified to answer an item, please indicate that in the appropriate section.
* An alternative format or template may be used so long as all required information indicated in this template is included.
* When submitting the completed review, include a CV or biography that includes information on your qualifications to serve as a scientific reviewer for this project.
* **Submit the review and CV or bio to the PI and the USMC IRB points of contact above.**

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| **Basic Information** | |
| Protocol Title: |  |
| Principal Investigator (PI) Name: |  |
| Review Date: |  |
| Scientific reviewer name, title, organization, and contact information: |  |
| Scientific reviewer’s relationship to the PI: |  |
| Scientific reviewer’s primary qualification(s) to review this project (e.g., academic or other professional credentials): |  |

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| **Research Design** | | |
|  | Purpose of the Research. Is / are the objectives / hypothesis clearly stated? What important problem or area of knowledge does the research address? How will scientific or scholarly knowledge be advanced if the research goals are achieved? | |
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|  | Theoretical Basis or Conceptual Framework. Assess the adequacy and appropriateness of the project’s theoretical basis or conceptual framework for the aims of the project. | |
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|  | Data Gathering Methods and Sampling. Assess the appropriateness of the methods proposed for gathering data in terms of the aims of the project and the research context. Is the sampling strategy and sample size appropriate for the project? | |
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|  | Data Analysis Methods. Assess the appropriateness of the methods proposed for analyzing the data in terms of the aims of the project and the type(s) of data that will be gathered. | |
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|  | Design Limitations. Are the limitations of different aspects of the design / approach clearly articulated? Please explain the basis for your determination. | |
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|  | Overall Design Appropriateness. Are the types of results this design can produce are appropriately matched with the scientific, scholarly, or programmatic claims the researchers hope to make? If they are not appropriately matched please explain why. | |
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|  | PI Design Awareness. Does the investigator recognize and acknowledge potential problem areas? How has the PI addressed those potential problem areas and what alternatives were considered? | |
|  |  | |
|  | Subject Selection. Are the inclusion and exclusion criteria appropriate for the aims of the research and the population? | |
|  |  | |
|  | Subject Availability. Are sufficient subjects available to support the research? Do you anticipate any problems recruiting sufficient subjects to support the research and, if so, how does the protocol address those potential problems? | |
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|  | **Principal Investigator and Research Team** | |
|  | Qualifications. Briefly describe how the qualifications of the PI and research team are adequate to carry out this work. If necessary, is there an appropriate plan to train the research team and other support personnel? | |
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|  | Supervision. If the PI is using a research team or research support personnel, explain whether the PI is trained and suited to supervise the team. | |
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|  | **Other** | |
|  | Please provide any additional information or recommendations you believe would be useful to the PI or the IRB. | |
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|  | **Recommendation** | **Check One** |
|  | The protocol is sound and the IRB should initiate its review. |  |
|  | The PI should make the following changes to the protocol to satisfy the scientific review (describe the changes in table cell below). |  |
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|  | The protocol will require major revisions and a second scientific review once revised (describe the revisions required in table cell below). |  |
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