**USMC IRB Protocol Personnel, Conflict of Interest, and Affirmation Worksheet**

THIS COVER SHEET MAY BE REMOVED PRIOR TO SUBMISSION

**USMC IRB Points of Contact**

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**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/).

**PURPOSE**: This worksheet is used to document (1) the personnel who will work on a protocol being submitted to the USMC IRB for review and (2) changes to personnel on approved protocols.

**GUIDANCE**

General:

* Before including individuals who are not USMC personnel or military/government personnel assigned to USMC (e.g., contractors or non-USMC research collaborators), contact your IRB Vice Chair or the USMC IRB POCs listed above for additional guidance.
* Fill out all applicable sections of this worksheet. 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.
* If you have questions, reach out to your IRB Vice Chair or the USMC IRB POCs listed above.
* This worksheet requires the Principal Investigator to certify that no conflicts of interest exist for any of the personnel who will work on the project. A full list of conflict of interest criteria/questions is available from the USMC IRB POCs listed above.

For initial reviews:

* Attach copies of CITI training certificates for all personnel and documentation of qualifications (bios, resumes, or CVs) for the Principal Investigator and all Associate Investigators.

For personnel changes:

* Verify that CITI training certificates for previously approved personnel are still current. If any are approaching the expiration date, arrange for the training to be renewed and attach copies.
* Verify that bios, resumes, or CVs for previously approved personnel are still current. If there have been any significant changes to qualifications or affiliation, attach updated documentation.
* Verify that no conflicts of interest exist for previously approved or new personnel.
* For all new personnel, attach copies of CITI training certificates and bios, resumes, or CVs.

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| **Protocol and Submission Information** | | | | | | |
| Protocol Number (if applicable): |  | | | | | |
| Protocol Title: |  | | | | | |
| Submission type (add an X next to the correct type): |  | Initial Review |  | Amendment |  | Continuing Review or Progress Report |
| Submission Date: |  | | | | | |

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| **Summary** | |
| 1. | Principal Investigator Contact Information. (include full name, title/position, organizational information, telephone number(s), and email address) |
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| 2. | PI Supervisor Contact Information. (include full name, title/position, organizational information, telephone number(s), and email address) |
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| 3. | Amendments ONLY: Briefly summarize the changes being made to the project team (additions and removals) and indicate if updated materials are being submitted for previously approved personnel. |
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| **Conflict of Interest** | |
| Contact your IRB Vice Chair or the IRB Chair if you have any questions or to report any potential conflicts of interest. | (Y/N) |
| Does the PI or any individual listed below have a significant financial interest in, or act as an officer or director of any outside entity whose financial interests may affect this research? |  |
| Does the PI or any individual listed below have existing financial holdings or relationships with the funding agency or sponsor of this project? |  |
| 1. Does the PI, any AI (if applicable), or any member of the PI’s or AI’s family/ies have interest or affiliations that could be seen as in conflict with your ability to conduct this research or as potentially affecting my commitment to the protection of human subjects? |  |

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| **Personnel** | | | | | | | |
| List all individuals involved with the project. All required training must be completed prior to engaging in the research. If the PI is changing, the new PI must be updated in the other applicable project materials (protocol, consent form, recruitment materials, etc.).  The PI is responsible for ensuring personnel have completed training, are qualified, and have no conflicts of interest, as well as for adherence to regulations and the overall ethical conduct of the project. | | | | | | | |
| List active project team members at the top of the list. Mark removal of personnel with red font. | | | | | | | |
| Roles  • PI - Principal Investigator (must be federal employee of USMC or service member assigned to USMC)  • AI - Associate Investigator  • Staff - Project Coordinator/Staff  • Other (provide description in Role column below) | | | | | | | |
| Service/Employment Codes  **1.** Marine  **2.** USMC government civilian employee  **3.** Other military service member (contact the USMC IRB POCs for additional guidance if individual is not assigned to USMC)  **4.** Contractor (contact the USMC IRB POCs for additional guidance)  **5.** Non-USMC research collaborator (contact the USMC IRB POCs for additional guidance) | | | | | | | |
| Activity Codes  **1.** Involved with recruitment and/or consent process  **2.** Involved in data collection, data entry, or storage of research documents and data  **3.** Involved with data (identifiable) analysis  **4.** Involved with administrative duties/tasks (no contact with subjects or data)  **5.** Supervisory role (no contact with subjects or data) | | | | | | | |
| Name & Rank or Title | Role | Email & Phone | Service or Employment Code | CITI Training  (Y/N) | Conflict of Interest? (Y/N) | New to Protocol?  (Y/N) | Activity Code (List all that apply) |
| 1) | PI | *(provided above)* |  |  |  |  |  |
| 2) |  |  |  |  |  |  |  |
| 3) |  |  |  |  |  |  |  |
| 4) |  |  |  |  |  |  |  |
| 5) |  |  |  |  |  |  |  |
| 6) |  |  |  |  |  |  |  |
| 7) |  |  |  |  |  |  |  |
| 8) |  |  |  |  |  |  |  |
| 9) |  |  |  |  |  |  |  |

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| **Investigator Affirmations** | | | |
| **NOTE: Electronic or ink signatures are acceptable for this section. This section may be submitted as a separate document if necessary to facilitate signatures.**  I acknowledge my responsibilities for performing and monitoring the research to be conducted under the protocol enclosed. I am familiar with and understand the provisions of:   1. DHHS Regulation, “Protection of Human Subjects,” (45 CFR Part 46 the “Common Rule”) 2. DoD Regulation, “Protection of Human Subjects,” (32 CFR Part 219) 3. DoD Instruction 3216.02 “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research” 4. SECNAVINST 3900.39 (Series), “Protection of Human Subjects,” 5. Privacy Act (5 USC 301, 552a) 6. USMC Human Research Protection Program Policy and Procedures   I will abide by all applicable regulations and policies that apply to this project and agree to abide by the determinations and decisions of the IRB and Institutional Official. If I have a question regarding my obligations during the conduct of the project, I have ready access to each of these regulations. I understand that my immediate resource for clarification of any issues related to the protection of research volunteers is the USMC IRB.  I attest to the above, that I do not have any conflict of interest, and that the documentation of my qualifications and training provided to the IRB is accurate. | | | |
| **Protocol #:** | | | |
| **Role** | **Printed Name** | **Signature** | **(MM//DD/YY)** |
| Principal Investigator |  |  |  |
| Associate Investigator |  |  |  |
| Associate Investigator |  |  |  |
| Associate Investigator |  |  |  |
| Associate Investigator |  |  |  |