**USMC IRB Full Protocol Template**

**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/)

**Instructions**

* This template should be used after a principal investigator (PI) has received a determination from the IRB that the planned project is human subjects research.
* 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 protocol.
* If you have questions about what to include or are not sure that a section applies to your project, reach out to the IRB staff.
* Ensure the contents of your materials match. For example, the description of how data will be protected that is provided in the informed consent document should not be substantively different from how data protections are described in the protocol.

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| **Protocol Information** | |
| Title of Research: |  |
| Planned Start Date: |  |
| Planned Completion Date: |  |
| Principal investigator name, command, and contact information: |  |

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| **Research Background and Design** | | | | | | | | | | | | | | | |
|  | | Provide background information on the origins of the project. | | | | | | | | | | | | | |
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|  | | Identify the project’s sponsor. If the research is being conducted independently by the PI, note that and list the PI’s command. | | | | | | | | | | | | | |
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|  | | Identify known, as well as potential, future users of the data / results. | | | | | | | | | | | | | |
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|  | | Briefly describe the objectives of the project. | | | | | | | | | | | | | |
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|  | | Briefly describe the research plan including both methods of data gathering and methods of data analysis. Ensure that the description includes a clear explanation of how the researcher team will interact with human subjects or their data. | | | | | | | | | | | | | |
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|  | | Describe why human subjects (or their data) must be used in the research. If there are alternatives, explain why they are not appropriate for the research. | | | | | | | | | | | | | |
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|  | | Where will the research take place? For projects involving in-person contact with subjects, list both the units and the physical location/installation. For projects using virtual means to contact subjects, list the units and/or installations from which subjects will be recruited. For projects using existing data, describe the organizations/systems from which you will get the data. | | | | | | | | | | | | | |
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|  | | When will recruiting and data collection take place? If your intent is to be flexible to accommodate unit and individual schedules, provide general date ranges. For projects using existing data, provide your best estimate of when you will request and receive the data. | | | | | | | | | | | | | |
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| **Information about Subjects** | | | | | | | | | | | | | | | |
|  | | Put an X in the box to the left of any category of participants that you plan to include. | | | | | | | | | | | | | |
|  |  | | Active duty Marines |  | Reserve Marines | |  | USMC civilian personnel |  | | DoD Contractors | | | | |
|  |  | | Members of other U.S. military services assigned to the USMC |  | Members of other U.S. military services not assigned to the USMC | |  | Employees of other federal agencies assigned to the USMC |  | | Employees of other federal agencies not assigned to the USMC | | | | |
|  | | Citizens of other countries assigned to a USMC command |  | Citizens of other countries not assigned to a USMC command | |  | Spouses of military personnel |  | | Dependent children of military personnel | | | | |
|  |  | | Poolees |  | Separated/retired military personnel | |  | Members of the public |  | | Other (describe below) | | | | |
|  | | Other: | | | | | | | | | | | | | |
|  | | Describe the population(s) about which you plan to make claims/from which your subjects will be drawn, including an estimate of the size of the overall population. | | | | | | | | | | | | | |
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|  | | Describe your sample size and sampling strategy. | | | | | | | | | | | | | |
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|  | | Inclusion criteria - describe the characteristics an individual needs to have to be eligible to be included. | | | | | | | | | | | | | |
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|  | | Exclusion criteria - describe the characteristics that would make an individual ineligible to be included. | | | | | | | | | | | | | |
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|  | | Describe how subjects will be recruited with particular attention to how command influence will be mitigated. Attach copies of recruiting materials including briefs, sample emails, flyers, draft social media posts, etc. | | | | | | | | | | | | | |
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| **Risks and Risk Mitigation** | | | | | | | | | | | | | | | |
| Note: All research with humans involves some risk, however small or unlikely. The objective in this section is not to show that the research is risk-free. The objective is to clearly articulate the risks and explain how and the extent to which you will mitigate them. | | | | | | | | | | | | | | | |
|  | | Do any of the questions / items / data elements that will be gathered in the research involve information that is private or sensitive? (Note that sensitive information may include, but is not limited to PII as defined by DoD. Consider information that your subjects may consider private or sensitive now or at a future point in their careers.) If yes, describe and assess the degree of potential risk or harm to the subject if disclosed. | | | | | | | | | | | | | |
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|  | | Describe the impact to the research if private or sensitive information could not be collected in the dataset. | | | | | | | | | | | | | |
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|  | | Describe the nature and extent of risks the collection and use of these data pose to the participants. Assess direct impact to the subject at the time of participation (physical, emotional), and possible future impact that the disclosure of the subject’s responses or other data could have on their financial standing, career, employability, insurability, reputation, etc. | | | | | | | | | | | | | |
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|  | | Describe precautions that are being used to minimize risk to the subject and safeguard the data. | | | | | | | | | | | | | |
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|  | | Describe any anticipated benefits to the participants, the Navy / Marine Corps, and / or society that may offset the risks to subjects. | | | | | | | | | | | | | |
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| **Voluntary Informed Consent** | | | | | | | | | | | | | | | |
| Note: Ensure that the informed consent materials you attach the protocol (e.g., informed consent agreement form, study information sheet, and/or verbal script) address the required elements of consent set out in the USMC HRPP Policy and Procedures. | | | | | | | | | | | | | | | |
|  | | Describe how you will ensure that participation in the research is voluntary with specific attention to steps you will take to mitigate command influence. | | | | | | | | | | | | | |
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|  | | Describe how subjects will be informed of their rights and the risks of participation. | | | | | | | | | | | | | |
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|  | | Are you requesting a waiver of the requirement to obtain informed consent? If yes, refer to Appendix F of the USMC HRPP Policy and Procedures and provide the rationale and applicable reference from 32CFR219. | | | | | | | | | | | | | |
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|  | | Are you requesting a waiver of the requirement to document informed consent? If yes, refer to Appendix F of the USMC HRPP Policy and Procedures and provide the rationale and applicable reference from 32CFR219. | | | | | | | | | | | | | |
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| **Compensation** | | | | | | | | | | | | | | | |
| NOTE: DoDI 3216.02 prohibits most types of compensation for participation in research for DoD-affiliated personnel while on duty. If you intend to compensate participants for participation while off duty, contact the HRPP to discuss requirements. | | | | | | | | | | | | | | | |
|  | | If applicable, describe the plan to compensate subjects for participation. | | | | | | | | | | | | | |
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| **Subjects’ Information and Identifiable Data** | | | | | | | | | | | | | | | |
| NOTE: The term “protected information” refers to information that the researchers have agreed to protect in the protocol and informed consent agreement. Protected information often (but not always) includes PII or PHI, but may not be limited to PII as defined by DoD. The standard of what information must be protected is always the protocol and informed consent agreement. | | | | | | | | | | | | | | | |
|  | | If applicable, describe how subjects’ name and other PII collected during recruiting or research for the purposes of scheduling, tracking, follow-up, or other purposes will be secured during the research and when/how it will be destroyed. | | | | | | | | | | | | | |
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|  | | If applicable, describe the process that will be used to remove information from the dataset prior to use in research outcomes. If subjects have been told that they will not be identifiable in research outcomes, carefully consider whether or not the “cleaned” dataset will include information that a person knowledgeable about the population could use to re-identify individuals (e.g., rare combinations of characteristics). | | | | | | | | | | | | | |
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| **Data Retention and Sharing** | | | | | | | | | | | | | | | |
|  | | After project completion the PI plans to: | | | | | | | | | | Yes | | | No |
|  | | Destroy all subject information and data from this project. | | | | | | | | | |  | | |  |
|  | | If yes to above, when will it be destroyed? | | | |  | | | | | |  | | | |
|  | | Retain information and data including identifying information. | | | | | | | | | |  | | |  |
|  | | Retain deidentified data. | | | | | | | | | |  | | |  |
|  | | Share retained data with other researchers. | | | | | | | | | |  | | |  |
|  | | Share retained data with others for non-research purposes. | | | | | | | | | |  | | |  |
|  | | Place retained data in one or more data repositories. | | | | | | | | | |  | | |  |
|  | | If data will be retained, describe the process(es) that will be used to ensure protected information continues to be stored and used in accordance with the protocol and informed consent agreement during retention and if shared and/or placed in a repository. | | | | | | | | | | | | | |
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| **Technology Use /User Agreements** | | | | | | | | | | | | | | | |
| Most commercial technologies used to organize research and gather and analyze data require the user (whether researcher or participant) to accept a user agreement. For example, many free cloud services used to back up photographs use the photographs to train their artificial intelligence tools and telephone applications often retain and sell user information and data. Use of these technologies can be highly effective. However, researchers must be aware of the implications of these agreements in terms of who will have access to participants’ information and the research data. Common technologies to consider include research software (e.g., analytic tools, transcription software, etc.), wearable devices and sensors, commercial cloud storage of files, and phone or tablet applications. | | | | | | | | | | | | | | | |
|  | | For projects that will use technology: | | | | | | | | | | Yes | No | | N/A |
|  | | Participants will be required to sign one or more user agreements for commercial technology used in this project. If the answer is “Yes,” provide a brief summary in the space below and attach copies of the user agreement. | | | | | | | | | |  |  | |  |
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|  | | One or more of the companies whose commercial technologies are used in the project will have access to participant’s identifying information and/or data. If the answer is “Yes,” provide a brief summary in the space below and attach a detailed explanation of what information and/or data will be accessible to the company and what the terms of their access are. For example, how they are allowed to use the information/data, how long they can retain it, whether or not it can be shared, etc. (NOTE: This may include not only technologies used by participants, but also other research tools.) | | | | | | | | | |  |  | |  |
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|  | | Researchers will make audio or video recordings, take photographs, or handle other research-related files using devices that will be backed up to a non-government cloud service. If the answer is “Yes,” provide a brief summary in the space below and attach a detailed explanation of what information and/or data will be accessible to the company providing device or cloud services and what the terms of their access are. For example, how they are allowed to use the information/data, how long they can retain it, whether or not it can be shared, etc. | | | | | | | | | |  |  | |  |
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| **Additional Reviews and Regulations** | | | | | | | | | | | | | | | |
|  | | To what other reviews, if any, is this study subject (e.g., Safety, Survey Program)? | | | | | | | | | | | | | |
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|  | | To what other regulations is this data collection effort subject (e.g., Privacy Act) and how will it / they be addressed? | | | | | | | | | | | | | |
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| **Submission Materials** | | | | | | | | | | | | | | | |
| Note: Use this section to list all materials that will be submitted with the protocol. Put an “X” in one of the columns to the right to indicate whether the item is included or not applicable. | | | | | | | | | | | | | | | |
|  | | Required Materials | | | | | | | | Included | | | | N/A | |
|  | | IRB Action Request (signed) | | | | | | | |  | | | |  | |
| Personnel Information Sheet/Conflict of Interest Statement/Investigator Affirmation Worksheet | | | | | | | |  | | | |  | |
| Documentation of required CITI training for PI and all research personnel who will be involved with recruiting subjects or working with subjects’ information or data. | | | | | | | |  | | | |  | |
| Documentation of qualifications for PI and AIs (resume, cv, or bio). | | | | | | | |  | | | |  | |
| Informed consent materials (e.g., agreement form, verbal script, study information sheet) unless a waiver of consent was requested. | | | | | | | |  | | | |  | |
| Recruiting materials unless the project involves only the use of existing data | | | | | | | |  | | | |  | |
|  | | Other Submission Materials | | | | | | | | Attached | | | | N/A | |
|  | | Notes:  1. The materials listed below may be required for some protocols. Consult with your organizational Vice Chair or the IRB about requirements for your project.  2. Add additional rows as needed to list all materials submitted. | | | | | | | |  | | | |  | |
|  | | Scientific Review | | | | | | | |  | | | |  | |
|  | | Commanding Officer Letter(s) of Support | | | | | | | |  | | | |  | |
|  | | Installation Letter(s) of Support | | | | | | | |  | | | |  | |
|  | | Technology User Agreements participants will be required to accept (e.g., for wearables, applications). | | | | | | | |  | | | |  | |
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