**PURPOSE:** The information on this worksheet allows the USMC Institutional Review Board (IRB) to determine whether or not your project meets the definition of human subjects research established in 32CFR219. This determination must be made and documented by the IRB.

**NOTE: If your submission is limited to evaluating a training session, class, course, or event and the results will be used only by the government officials responsible for the program, contact the IRB for a short version of this template:**

Some of the terms and questions on this worksheet may be unfamiliar to individuals who are not researchers. If you have questions or need assistance completing this worksheet, contact your organization’s Vice Chair or IRB point of contact. You also may contact the IRB directly:

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| Dr. Kerry Fosher  IRB Chair  Director, Human Research Protection Program  kerry.fosher@usmcu.edu | 571-289-6448 | (*Position Vacant*)  IRB Administrator  Human Research Protection Program Specialist |

**References**

The primary reference for this worksheet 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**

* 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.
* If using acronyms (other than USMC and HQMC), provide the full term prior to the first use of the acronym, e.g., “Marine Corps University (MCU).”
* If you have questions about what to include, reach out to your Vice Chair or the IRB staff.
* NOTE: Other reviewing offices, such as the USMC Survey Program may need additional information and have other forms that need to be completed.

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| **Submission Information** | |
| **Project Title**: |  |
| **Name, command, and contact information for the principal investigator (PI) or person responsible for the project**: |  |
| **Planned dates of the project**: (If the project will be ongoing, such as an annual survey, list the planned start date and that it will be ongoing, e.g., “24 Nov 2024 – ongoing [annual]”) |  |

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| **Baseline Project Information** | | | |
|  | Summarize the background of the project. Why did you decide to conduct it? | | |
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|  | Summarize your objectives. What do you hope to gain from the project? | | |
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|  | Do you expect to make claims about or develop insights about a group beyond the specific people who participate? (e.g., drawing conclusions about infantry Marines in general based on a survey of 2,000 infantry Marines.) | | |
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|  | Is the project an assessment of a program? If so, will the results be used by anyone other than the government officials responsible for the program? For example, do you plan to aggregate the information with other projects for research purposes, publish a Gazette article, or share the results with others? | | |
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|  | Will participants be identifiable in the information you gather? (i.e., will their names and/or other identifying characteristics or markers, such as EDIPI, be included? is it possible that individuals with unusual combinations of characteristics, such as a rare combination of sex, MOS, and location, could be identified by somebody knowledgeable about the population?) | | |
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|  | Will you be gathering private information? Private information is defined in 32CFR219. It includes information such as anything that a participant might say or do during the project that they otherwise would not make public, information gathered in a context in which a participant has a reasonable expectation that no observation or recording is taking place, or information included in existing datasets that the participant provided for a specific purpose and had a reasonable expectation that it would not be made public. | | |
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| **Project Participants** | | | |
|  | Describe the participants who will be eligible to participate (e.g., all active duty and reserve Marines at a specific location, active duty enlisted Marines with a specific MOS, or civilian personnel with specific demographic characteristics). Be specific about characteristics such as civilian/military, active duty/reserve, officers/enlisted, sex, etc. | | |
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|  | Who will be excluded as participants? (For many projects, the only participants who will be excluded are those who do not meet the criteria in #6 above. If so, state that.) | | |
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|  | How many individuals do you estimate will participate from each of the categories listed in #7 above? If the project will be ongoing, provide an estimate of the annual number of participants. | | |
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| **Potential Risks** | | | |
| **Note**: All information gathering from people involves some risk, however small or unlikely. The objective in this section is not to show that the project is risk-free. The objective is to clearly articulate the risks. | | | |
|  | What are the possible risks to participants? Consider not only risks during the project, but future risks from potential issues such as accidental release of information. | | |
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|  | Explain why the benefits outweigh the risks of the project. | | |
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|  | If information gathered for the project was accidentally disclosed, is it possible that one or more participants could be at risk of criminal or civil liability or damage to their financial standing, employability, educational advancement, or reputation? | | |
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| **Methods** | | | |
|  | Where and when do you plan to conduct the project?   * When addressing location, if this project will be conducted across the entire service (e.g., a large survey) note that. Otherwise, list both the units involved and the physical locations (e.g., the USMC installations). * When addressing when information will be gathered, indicate if you have specific date requirements or if you are able to flex your activities to accommodate unit schedules. | | |
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|  | How will information be gathered? (e.g., interviews, surveys, focus groups, observations, use of existing datasets) | | |
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|  | How will information be analyzed? (e.g., statistical analysis, thematic analysis, etc.) | | |
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|  | Who will gather the information? Who will conduct the analysis? | | |
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| **Information Gathering Details**  (attach separately) | | | |
|  |  | **Attached** | **N/A** |
|  | **For projects involving surveys, questionnaires, interviews, or focus groups:** Attach information gathering instruments or sample questions. Questions do not have to be finalized at this stage, but the examples provided must be sufficient for the IRB to understand the range of topics that will be covered and the types of perspectives orknowledge participants will be asked to share. |  |  |
|  | **For projects involving use of existing datasets:** Attach a list of the organization(s) from which you will request data and a list of what data fields you will request. |  |  |

**Principal Investigator/Responsible Party Acknowledgement.** By submitting this document, you acknowledge that you will not recruit participants or gather information or data from/about participants until you receive a determination that the project is not human subjects research from the IRB or, if the project is determined to be human subjects research, until your full protocol has been approved by the IRB and, if applicable, the Institutional Official. You also acknowledge that you understand that your immediate resource for clarification of any issues related to the protection of research volunteers is the USMC IRB, that other USMC or external reviews may be required based on the details of your submission, and that the requirements and timelines for other reviews are outside the control of the USMC IRB. Additional information may be found in MCO 3900.18 and the USMC HRPP Policy and Procedures, available on the HRPP public website (<https://www.tecom.marines.mil/Resources/USMC-Human-Research-Protection-Program/>)