**USMC IRB Final Report Template**

**USMC IRB Points of Contact**

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**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**

* Use this template to submit a final report.
* 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 staff.

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| **Protocol Information** |
| Protocol Number: |  |
| Protocol Title: |  |
| Principal investigator name, command, and contact information: |  |
| Full date range of protocol (starting date to completion date) |  |

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| **Objectives, Execution, and Results** |
| 1. | Summarize the research objectives. |
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| 2. | Summarize research performed focusing on human subjects involvement. |
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| 3. | Summarize the demographics of subjects to include the total number of subjects who gave consent to participate and a breakdown according to characteristics relevant to the research. |
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| 4. | Describe any significant issues that have occurred, particularly those that may relate to human subjects issues, such as unplanned delays affecting the selection or use of human subjects, complaints received from subjects or others, adverse events, and unanticipated problems. |
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| 5. | Summarize any research design or execution lessons learned or problems with study methodology (including informed consent process) particularly as they relate to the protection of human subjects. |
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| 6. | Summarize research results and completed/planned research outcomes (reports, briefs, publications, etc.). |
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| 7. | Summarize the benefits of the research. |
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| **Subject Information and 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, 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. Data may not be retained, shared, or placed in a repository unless the informed consent language used in the protocol explained that possibility to subjects.  |
| 8. | Have all paper and digital copies of material (other than data) including protected information used during recruitment, scheduling, tracking, and follow-up (e.g., schedules, code keys) been destroyed?  |  | Yes |  | No |
| 9. | Have all paper and digital copies of data including protected information been destroyed?  |  | Yes |  | No |
| 10.  | If the answer to either #8 or #9 is “No” explain what specific protected information is being retained, why, how long it will be retained, and how it will be secured until destruction. |
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| 11. | Will data from this protocol be retained for future use by the PI/research team? |  | Yes |  | No |
| 12. | If the answer to #11 is “Yes,” describe the process that was used to remove protected information from the dataset or explain the reason for retaining raw data.  |
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| 13. | If the answer to #11 is “Yes,” describe the specific procedures that will be used to ensure that the protections afforded to subjects in the original informed consent will be maintained during future use. |
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| 14. | Will data from this protocol be shared with other researchers in the future? |  | Yes |  | No |
| 15.  | If the answer to #14 is “Yes,” describe the specific procedures that will be used to ensure that the protections afforded to subjects in the original informed consent will be maintained during future use. |
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| 15. | Will data from this protocol be put in a data repository? |  | Yes |  | No |
| 16. | If the answer to #15 is “Yes,” list the repository/ies you are considering and describe the specific procedures that will be used to ensure that the protections afforded to subjects in the original informed consent will be maintained during future use. |
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| **Submission Materials** |
| NOTE: Use this section to list all materials that will be submitted with the final report. Put an “X” in one of the columns to the right to indicate whether the item is included or not applicable.  |
| 17. | Required Materials | Included | N/A |
|  | IRB Action Request (signed) |  |  |
| Personnel Information Sheet/Conflict of Interest Statement/Investigator Affirmation Worksheet updated with all current protocol personnel (if no changes have been made since the last Continuing Review or Progress Report, you may include the last worksheet submitted and note “no changes” in the table cell to the right) |  |  |
| Research outcomes (list each outcome separately in section 18 below) |  |  |
| 18. | Other Submission Materials |
|  | NOTES: 1. Add additional rows as needed to list all other materials submitted.2. For research outcomes, list each separately. Research outcomes may include a range of items such as reports, publications, briefs, training modules, information papers, etc.  |
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