U.S. Army Public Health Center (APHC)
Office of Human Protections - Modification Determination

#21-931.M1 COVID-19 Vaccination Perceptions and Messaging Formative Evaluation

Project Timeline**:** (see enclosed timeline for details)
14 July 2021 received approved updated data protection plan.
14 July 2021 received project modification via email.
15 July 2021 forwarded to Dr Jones for Scientific Review.
17 July 2021 Scientific Review Memo forwarded from Dr Bruce Jones.
19 July 2021 OHP received updated project modification following Scientific Review suggested edits.

The changes in this modification are summarized below:

1. Modified the objectives to capture perceptions and beliefs regarding a potential COVID-19 vaccination mandate, including:
   a. Revised first objective "Identify perceptions of and factors affecting COVID-19 vaccination at the installation level" to "Identify perceptions, and the factors that shape these perceptions, in regard to the potential of mandatory COVID-19 vaccination among installation personnel."
   b. Deleted the objective: "Understand awareness and perceptions of APHC messaging developed by PHCOM surrounding COVID-19 and COVID-19 vaccine uptake."
   c. Added the objective: "Understand information needs of installation personnel if COVID-19 vaccination were to be mandated."
2. Modified the guiding questions to capture perceptions and beliefs regarding a potential COVID-19 vaccination mandate, including:
   a. Revised first guiding question "What perceptions, beliefs, attitudes and behaviors exist among MTF personnel and the broader installation population related to COVID-19 and COVID-19 vaccination?" to "What perceptions, beliefs and attitudes exist among installation personnel related to COVID-19 vaccination becoming mandatory?"
   b. Revised second guiding question "What factors (i.e., facilitators/barriers) affect COVID-19 vaccine uptake and hesitancy at the installation level?" to "What factors (i.e., facilitators/barriers) impact mandatory COVID-19 vaccination perceptions among installation personnel?"
   c. Deleted guiding question: "How aware are participants of APHC COVID-19 and COVID-19 vaccine/vaccination messaging?"
   d. Added guiding question: "What information needs do interviewees anticipate among installation personnel if COVID-19 vaccination were to be mandated?"
   e. Revised fourth guiding question "What are participant perceptions and suggestions regarding the APHC COVID-19 vaccination messaging concepts?" to "What are participant perceptions and suggestions regarding APHC mandatory COVID-19 vaccination messaging concepts?"

3. Updated the target population to include Command Surgeons, in addition to the target population of Public Health Emergency Officers (PHEOs) and Assistant Public Health Emergency Officers (APHEOs) previously approved in OHP Project Plan #21-931.

4. Revised the data collection approach to two focus groups, one focus group of PHEOs and another focus group of Command Surgeons, and, as necessary depending on OCONUS participant availability, 1-2 key informant interviews.

5. Revised sampling strategy to convenience sampling only, without snowball sampling augmentation.

6. Audio recordings will not be transcribed for this phase of data collection.

7. Updated the timeline and deliverables.

8. Updated the list of project personnel who will support data collection, analyses and reporting.

9. Developed a semi-structured focus group/interview guide to align with the modified objectives and guiding questions.

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#21-931.M1 COVID-19 Vaccination Perceptions and Messaging Formative Evaluation (cont-)

This is a continuation/modification of the previously approved Rapid Response and Full Project Submissions for #21-931 'COVID-19 Vaccination Perceptions and Messaging Formative Evaluation'

20 July 2021 Human Protections Director (HPD) Determination: The modification does not change the original determination of not research - public health practice. This request has been; Approved.

REPORTING OBLIGATIONS:
All data must be protected at all times and it is incumbent of the Project Lead to instruct and oversee any intern or other staff on the proper data protection strategies.

Please note the following reporting obligations are required to be provided in writing to the Human Protections Director (HPD) and the Office of Human Protections (OHP) for review and/or approval:

1. Submit a Modification Form for any deviation or modification to the activity in the approved project plan prior to implementing the change.
2. Submit a Modification Form if the Project Lead is being changed on the project.
3. Immediately report all unanticipated problems involving risks to human subjects, serious adverse events related to the activity population, and / or data loss, breach, leakage, or spillage.

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Dawn Gyory	Human Protections Director	410.417.2611	dawn.m.gyory.civ@mail.mil

Public health practice projects are not research as defined by Section 219.101, Title 32, Code of Federal Regulations, and do not require Institutional Review Board review or approval. Per DODI 3216.02 Protection of Human Subjects and Adherence to Ethical Standards in DOD-Conducted and Supported Research, the following activities conducted or supported by the DOD are not considered human subject research: activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease under force health protection programs of DOD, including health surveillance pursuant to Section 1074f of Title 10, U.S.C., and the use of medical products consistent with DODI 6200.02.

The determination of public health practice is applicable to the APHC personnel who are engaged in the activities as described in this project plan. This determination may be of consideration to non-APHC personnel who are engaged in the project, but it should be recognized that the local and institutional policies and regulations on human research protection programs still apply.