



UNITED STATES MARINE CORPS
TRAINING AND EDUCATION COMMAND
2007 ELLIOT ROAD
QUANTICO VIRGINIA 22134-5112

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HRPP
17 Dec 25

USMC HUMAN RESEARCH PROTECTION PROGRAM POLICY LETTER 01-26

From: Institutional Official, USMC Human Research Protection Program
To: Director, USMC Human Research Protection Program

Subj: LIMITATIONS ON RETENTION AND FUTURE USES OF BIOSPECIMENS, GENETIC DATA, GENOMIC DATA, AND RELATED INFORMATION AND DATA FROM USMC PARTICIPANTS IN HUMAN SUBJECTS RESEARCH

Ref: (a) 32 CFR 219
(b) DoDI 3216.02 CH-1 (series)
(c) SECNAVINST 3900.39E CH-1 (series)
(d) MCO 3900.18 (series)
(e) USMC HRPP Policy and Procedures
(f) Public Law 110-233

1. Situation. In accordance with references (a) through (e), the USMC Human Research Protection Program (HRPP) reviews and oversees all human subjects research conducted or supported by the USMC, including provisions for retention, future use, and sharing of the information gathered or developed in the research. This policy letter provides guidance to supplement reference (e) for human subjects research that involves biospecimens, genetic data, genomic data, and /or related information and data from USMC personnel.

2. Cancellation. Not applicable.

3. Mission. An increasing number of projects submitted to the USMC HRPP involve using, gathering, and /or developing biospecimens, genetic data, and /or genomic data. Such materials pose individual and aggregate risks. Many such research protocols include provisions for retention, future uses, and sharing of such materials without further consent from participants. These provisions rarely contain limitations on the types of research in which they may be used. For example, a blood sample gathered to measure glucose could be repurposed for genomic research. The pace of development in research technologies makes it challenging to anticipate all potential future uses of biological materials and data. Reference (f), the Genetic Information Nondiscrimination Act of 2008, affords civilians some protections against discrimination based on genetic information, but does not apply to military personnel. Reference (b) places constraints on large-scale genomic research, but does not address smaller projects or provide explicit approval criteria.

4. Execution

a. Commander's Intent and Concept of Operations

(1) Commanders Intent. The USMC HRPP takes appropriate measures to mitigate the individual and aggregate risks associated with the use, gathering, and/or development of biospecimens, genetic data, genomic data, and /or related information and data in human subjects research.

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(2) Concept of Operations. For human subjects research that involves using, gathering, and /or developing biospecimens, genetic data, genomic data, and /or related information and data, the USMC HRPP shall take extra precautions in considering how these materials are handled during the research, retention, future uses, and sharing.

(a) The USMC HRPP shall approve human subjects research involving such materials only when the following criteria are met in addition to existing requirements:

1. The protocol and informed consent provide a detailed explanation of whether and how information will be de-identified before retention and future uses or sharing.

2. The de-identification plan, if applicable, is tailored for the specific, targeted population and significantly reduces the risk of re-identification.

3. The explanations of the data de-identification plan and plans for collection, retention, future uses, and sharing provided in the informed consent document are written in a style and format appropriate for the specific, targeted population.

4. If the sharing plan includes placing the materials in a data repository, the USMC HRPP receives and approves detailed information about the repository, including its data access and use policies and information security arrangements. The data repository must be Core Trust certified, on the National Institutes of Health list of supported repositories, or meet equivalent standards. Unless the researcher is able to provide a substantive justification for pay- or institutional membership-walled repository, the data repository must be freely accessible (other than appropriate access controls) regardless of a user's institutional affiliation or paid membership.

(b) The researcher and, if applicable, sponsor and appropriate authority for the data repository, must agree to accept the following approval contingencies even if the informed consent agreement indicates unrestricted future uses. Materials covered by this policy:

(1) May not be used (other than for the approved protocol) or shared without the written permission of the USMC HRPP Institutional Official.

(2) Will be marked with this restriction at the time they are prepared for retention.

(c) Exceptions to this policy require written authorization from the USMC HRPP Institutional Official.

(d) The USMC HRPP Director may issue supplemental materials, such as procedures and guidelines, as needed to implement this policy.

c. Coordinating Instructions. Not applicable.

5. Administration and Logistics

a. Administration

(1) Recommendations. Submit all recommendations concerning this policy to the USMC HRPP via the appropriate chain of command.

(2) Records management. Records created because of this policy shall be managed according to National Archives and Records Administration (NARA)-approved dispositions per SECNAV M-5210.1 CH-1 to ensure proper maintenance, use, accessibility, and preservation, regardless of format or medium.

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b. Logistics. Not applicable.

6. Command and Signal

a. Command. This policy is applicable to all internal and external human subjects research covered by reference (d).

b. Signal. This policy is effective the date signed.

A handwritten signature in black ink, appearing to read 'A. J. Greco, Jr.', with a stylized flourish at the end.

A. J. GRECO, JR.

Distribution: A