SUMMARY STATEMENT

(Privileged Communication)

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PROGRAM CONTACT:
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Application Number: 1 R03 HG006730-01

Principal Investigator

MEHLMAN, MAXWELL J JD

Applicant Organization: CASE WESTERN RESERVE UNIVERSITY

Review Group: ZRG1 HDM-T (90)
Center for Scientific Review Special Emphasis Panel
Multidisciplinary Healthcare Delivery Research AREA Grant Applications

Meeting Date: 10/17/2011
Council: JAN 2012
Requested Start: 04/01/2012

RFA/PA: PA10-064
PCC: X5JB

Project Title: Ethical, Legal, and Social Implications in Military Genomics

SRG Action: Priority Score

Human Subjects: 10-No human subjects involved

Animal Subjects: 10-No live vertebrate animals involved for competing appl.

Project Year	Direct Costs Requested
1	50,000
2	25,000
TOTAL	75,000

DC Recommended

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

1R03HG006730-01 MEHLMAN, MAXWELL

RESUME AND SUMMARY OF DISCUSSION: This study addresses a significant topic of plore ethical legal and social issues of genomics studies in the military. The investigator has access to large banks of DNA and the study has potential to improve general medical care in military members and civilians. The reviewers noted that the investigator is extremely experience and is supported by an advisory group. The investigator makes a good argument for the needed study and shows logical development of an ethical framework. There were some minor weaknesses raised by the reviewers and include sparse literature review; methods that are not innovative though appropriate; lack of discussion on engagement of advisors in the project; and lack of collaboration with other researchers such as clinical geneticists to enhance translational research. Overall the strengths greatly outweigh the weaknesses of this significant study.

DESCRIPTION (provided by applicant): Advances in genomic science are attracting the interest of the U.S. military for their potential to improve medical care for members of the military and to aid in military recruitment, training and specialization, and mission accomplishment. In addition, large DNA banks operated by the military could be a valuable resource for military and civilian researchers. While ELSI research projects have explored issues raised by the use of genomic science in a wide variety of contexts, there has been virtually no examination of the ethical, legal, and social issues raised by military genomics beyond those relating to forensic use of the Department of Defense (DoD) DNA Registry. This project will bring the insights from the ELSI program and the broader conversation on the ethical, legal, and social issues posed by genomic science in general to bear on the unique challenges presented by potential uses of genomic science by the military. Building on work now underway to develop a bioethical framework for military bioenhancement, this project will construct the first bioethical and legal framework for military genomics, and will employ this framework to analyze how ELSI issues might be resolved.

PUBLIC HEALTH RELEVANCE: This project will construct an ethical and legal framework for military genomics and apply this framework would apply to uses of genomic science contemplated by the U.S. military. This will promote the public health by elucidating ethically and legally appropriate ways to construct and utilize a proposed new military/VA DNA biobank, and by offering suggestions for how to protect the health and well-being of members of the military and their families as the military increases its uses of genomics.

CRITIQUE 1:

Significance: 2
Investigator(s): 1
Innovation: 3
Approach: 4
Environment: 2

Overall Impact: Given the putative uses of genomics for military and defense purposes and the growth of that technology, ethical issues are paramount. Technology development generally brings new ethical issues and concerns which need to be disseminated to appropriate groups. The ethical issues that are identified may well go beyond the classical bioethical principals that are applied to general biomedicine. These issues may have implications for other genome technology development as well

1. Significance:

Strengths

- This application presents a good argument for the timeliness and importance of developing an ethical and legal and social impact framework for the emergent development of genomic technology being developed by the military department of defense.
- The ethical issues in the military context are highlighted and contrasted with the ELSI genome project for the civilian context, which imply that additional study needs to be done.

Weaknesses

- The literature review is a bit sparse and doesn't fully identify the gap in the ethical literature; however, some of this may be due to some of the issues being classified.

2. Investigator(s):

Strengths

- The PI has extensive background in both ELSI and military bioethics
- The project advisory committee members have outstanding credentials.
- The advisory committee represents a variety of expertise.

Weaknesses

- None noted.

3. Innovation:

Strengths

- The systematic approach with input from a variety of experts, both within and outside the military, is a solid and needed approach.

Weaknesses

- None noted.

4. Approach:

Strengths

- The methodology of literature synthesis and applying principles from law and ethics to develop a framework and applying that framework to potential cases seems appropriate.
- This application mentions initiating critical conversations with geneticists, bioethicists, legal experts, military planners, veterans groups and policy makers which would be appropriate for scholarly development of an ethical framework.
- The project advisory committee is comprised of ethical and legal experts representing both the military and general bioethics.

Weaknesses

- While the advisory committee membership is a strength, and the methods suggest a conversational perspective with experts; it is not clear from the approach how they will be

engaged in the actual development of this framework. Additionally, they are not a line item to be supported for their time commitment.

5. Environment:

Strengths

- The Law-Medicine Center of Case Western Reserve University is the site for the study.

Weaknesses

- None noted.

Protections for Human Subjects:

Not Applicable (No Human Subjects)

Inclusion of Women, Minorities and Children:

- NA

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Budget and Period of Support:

Recommend as Requested

CRITIQUE 2:

Significance: 1
Investigator(s): 2
Innovation: 2
Approach: 2
Environment: 1

Overall Impact: This project will construct the first bioethical and legal framework for military genomics, and will employ this framework to analyze how ELSI issues might be resolved. This will promote the public health by elucidating ethically and legally appropriate ways to construct and utilize a proposed new military/VA DNA biobank, and by offering suggestions for how to protect the health and well-being of members of the military and their families as the military increases its uses of genomics. As the military is one of the few institutions in the United States that has large biobanks and population-based genomic registries, this proposal will be a very interesting opportunity to look at ELSI issues.

1. Significance:

Strengths

- Military genomics is an important area
- The military has population-based genomic information in the US – there are not too many other repositories as large as this in the US (aside from newborn screening)

Weaknesses

- The title of the proposal doesn't quite capture what is being studied

2. Investigator(s):

Strengths

- Professor Mehlman has appropriate training in ELSI issues
- Strong track record
- Appreciate the involvement of military personnel on the advisory committee

Weaknesses

- Would be nice to have a clinical geneticist collaborator to enhance assessment of clinical and translational issues

3. Innovation:

Strengths

- Looking at genomics in the military using an ELSI framework is innovative.
- Great topic

Weaknesses

- The approach is not particularly innovative

4. Approach:

Strengths

- The approach is straightforward academic inquiry, supported by an advisory committee
- The advisory committee brings tremendous expertise from a variety of disciplines to this proposal
- Previous grant lays the groundwork for this proposal

Weaknesses

- Professor Mehlman seems to be running a one-man shop supported by research assistants, as opposed to building an interdisciplinary research team that would integrate various disciplines

5. Environment:

Strengths

- Law school and Case Western provide an outstanding academic environment
- Great letters of support

Weaknesses

- None noted.

Protections for Human Subjects:

Not Applicable (No Human Subjects)

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

CRITIQUE 3:

Significance: 2
Investigator(s): 1
Innovation: 2
Approach: 4
Environment: 2

Overall Impact: The proposed project will adapt current ELSI research on use of genomics to military personnel. The PI has proposed an impressive advisory body, although the extent to which they will be actively involved in developing the framework isn't well-specified. The application goal of the proposal is to resolve identified ethical issues; however the study team has only a limited set of the potential stakeholders, raising concerns of preference bias in the choice of solutions.

Protections for Human Subjects:

Not Applicable (No Human Subjects)

Inclusion of Women, Minorities and Children:

G1A - Both Genders, Acceptable

M1A - Minority and Non-minority, Acceptable

C3A - No Children Included, Acceptable

- Target population military service personnel

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Budget and Period of Support:

Recommend as Requested

THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-10-080 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-080.html.

The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.