



INSTITUTE OF MEDICINE

OF THE NATIONAL ACADEMIES

REQUEST FOR PROPOSAL

Announced September 10, 2012

DESCRIPTION

Purpose

The Institute of Medicine (IOM) has assumed custody of the data and biospecimens collected during the Air Force Health Study (AFHS), also known as the “Ranch Hand Study,” that was conducted between 1979 and 2006 and is now making these materials available for further scientific study. This announcement solicits applications to access the data and biospecimens.

Background

In 1979, the US Congress directed that an epidemiologic study be conducted of the frequency and nature of adverse health effects possibly related to exposure to “Agent Orange” and other military herbicides used during the Vietnam Conflict. The effort—formally called the *Air Force Health Study*—studied veterans involved in herbicide spraying missions and a comparison group. Data and biospecimens were collected in 6 cycles over 20 years (i.e., in 1982, 1985, 1987, 1992, 1997, and 2002). In all, 2,758 subjects participated in at least one exam.

Current data are available from, among other things, blood, urine and semen samples; skin and fat biopsies; stool smears; spirometry; chest X-rays; electrocardiograms; dermatological, neurological and peripheral vascular examinations; and psychological testing. Medical records for the study subjects were provided and interviewer-led questionnaires eliciting information on education; employment; income; marital and fertility history; child and family health; personal health habits; recreation, leisure, and physical activities; possible exposure to toxic substances; military experience; and wartime herbicide exposure were also obtained.

More than 86,000 biologic specimens were collected over the course of the study; approximately half of these are serum. Serum was collected from study subjects in all six cycles. Semen was obtained in the first cycle of testing and urine in Cycles 1-3 (1982, 1985, and 1987). Adipose tissue biopsies were collected during Cycle 5. Whole blood was also collected in Cycle 6.

The AFHS per se has concluded and these research assets are now being made available to a broader set of researchers to allow for additional investigation. IOM envisions such investigations including:

- Reanalysis of outcomes examined by the AFHS using new or different assumptions and approaches;
- Analyses that examine questions not addressed in the AFHS;
- Studies that take advantage of advances in technology or science;

- Extension of the study's period of analysis through follow-up of the cohorts using publicly available information, and
- Additional follow-up of health outcomes tracked in the original study.

Cost estimates for preparing specimen aliquots and shipping (if applicable) will be provided upon request.

Further details about the AFHS, its research subjects, and the data and biospecimens collected may be found at www.iom.edu/afhs and in the IOM report [Disposition of the Air Force Health Study](#), which may be freely downloaded from the National Academies Press website.

Objectives

The goal of this program is to provide researchers with access to the AFHS data and biospecimens to further medical knowledge while also maintaining the privacy and confidentiality of the study participants.

AWARD INFORMATION

Project period

The scope of proposed projects will determine the appropriate project period. IOM anticipates that projects looking to use only data should be able to complete their research within 2 years. Those projects approved to use biospecimens should be able to complete the analysis of the specimens within one year of receipt, and complete the entire project, including data analysis, by the end of the second year.

ELIGIBILITY INFORMATION

Eligible organizations

All types of organizations (including government, non-profit, and for-profit) are eligible to apply for access to the data and biospecimens, including institutions outside the United States.

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

APPLICATION AND SUBMISSION INFORMATION

Application package

Applicants must go to www.iom.edu/afhs and follow the link to Survey Gizmo to fill out the letter of intent. Letters of intent describing studies that are deemed feasible will be notified via email by the IOM and will be provided a separate link to enter the proposal. Only electronically submitted applications will be considered.

Applicants must provide all required information for a letter of intent (LOI) or proposal to be considered; applications will not be considered complete until all information is received. Incomplete applications will not be reviewed.

The proposal format is modeled after the NIH R01 proposal form. The research plan may not exceed 6 pages in length. Principal investigators' biographies may not exceed 4 pages in length.

Submission dates

LOIs received by October 1, 2012, if approved, will receive priority consideration. Decisions about the feasibility of a study will be made within 2 weeks, and applicants will be notified of approval decisions by email. LOIs received after October 1, 2012 will still be considered but may be given lower priority.

Proposals should be submitted within 3 weeks of notification of the LOI being approved to meet the November 1 submission deadline. Applicants may resubmit a proposal once.

APPLICATION REVIEW INFORMATION

Criteria

A LOI is required to determine feasibility based on the availability of data and/or biospecimens requested. After a LOI is approved, a full proposal must be submitted for review.

Proposals will be evaluated for scientific merit using the following criteria:

1. The issue being addressed is of considerable scientific and/or medical interest.
2. The study design is appropriate.
3. The sample size is sufficient. For example, statistical power calculations might be provided to justify the sample size.
4. The investigator or investigative team have appropriate qualifications and experience to conduct the study.
5. The proposal demonstrates the researcher's familiarity with the relevant literature.
6. The proposed work cannot be undertaken without data and/or specimens collected from the AFHS.
7. The researchers have provided sufficient evidence that they can perform to accepted standards, including quality control, data security, laboratory analytical standards, and data analysis.
8. If the study requires the IOM to contact members of the cohort to obtain additional information, extra expenses may be incurred. The costs of obtaining these data and addressing any relevant ethical and consent issues must be addressed adequately.
9. The researchers have or are able to obtain sufficient funds to conduct the study.

10. The researchers and any collaborators are qualified to appropriately select and perform the statistical analyses required for the study and to properly interpret the results.
11. The researchers have identified suitably qualified and trained persons to perform the work, and agree that only these persons will have access to the specimens and to the data which are either provided or generated from the specimens.
12. The researchers have provided assurance that they will maintain specimens (if applicable) and data under secure and confidential conditions.
13. The amounts of specimens requested by the researchers are appropriate for the study, and are not excessive, given the limited availability of the specimens (if applicable).

Review and selection process

Independent peer reviewers will be asked to evaluate each proposal. The IOM will provide applicants a written critique. If applicable, applicants may be asked to respond specifically to the critique before a final decision is made.

Anticipated announcement/award dates

Decisions will be made in a timely manner after the peer review process is complete.

Human subjects protection

All proposals will need to be approved by the principal investigator's local Institutional Review Board (IRB). The IRB of the National Academy of Sciences will review approved proposals. Applicants may need to revise their proposal based on the recommendation of the National Academy of Sciences' IRB. Data and/or biospecimens will not be distributed until both the local and National Academy of Sciences' IRBs approve the proposal.

A formal notification will be made to the principal investigator after the peer review process is complete and both the local and National Academy of Sciences' IRBs approve the proposal.

FUNDING

Investigators are responsible typically for obtaining their own research funding, independent of the IOM. The IOM's limited funds will be used only to support the most meritorious pilot studies and small-scale research projects. Up to 10 percent of awarded funds may be applied to indirect costs. The IOM anticipates making up to 2 awards of approximately \$50,000 each. The IOM reserves the right to adjust the number or size of awards. Awarded funds must be used by June 30, 2013. To apply for funds, please indicate so in the LOI, and we will contact you by email. There is no difference between the proposals or the evaluation criteria for those seeking funding and those not seeking funding.

CONTACTS

Questions should be directed to AFHS-study@nas.edu.