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Medical Command

**CLINICAL INVESTIGATION AND HUMAN
USE IN MEDICAL RESEARCH**

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(Col Gerald J. Merritt)
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1. Scientific studies are an essential component of medical practice, graduate medical education, and the development of leading edge technology to support Air Force missions. Patients and healthy subjects are used in these studies. Because such studies may expose subjects to risk, it is imperative these studies be well-designed and that subjects are fully aware of, and give consent to participate in this research. This directive establishes policies for managing risk, ensuring informed consent, and assuring scientific validity of these studies.
2. The Air Force will establish a Clinical Investigation and Human Use Program (CIHUP) in human-use laboratories, Clinical Investigation Facilities (CIF) and Medical Treatment Facilities (MTF) to conduct scientific studies in support of Air Force aeronautical and or aeromedical missions.
 - 2.1. Human-Use Program Laboratories will be used to conduct research, development, test, and evaluation (RDT&E) studies that involve human subjects.
 - 2.2. The Air Force Medical Service will establish CIFs at MTFs to conduct scientific studies with the potential to improve patient treatment, diagnosis, or well-being.
3. The Air Force will fully comply with all applicable Federal regulations to ensure the protection of human subjects.
 - 3.1. All studies will use procedures which are consistent with scientifically valid research design and which do not unnecessarily expose subjects to risk.
 - 3.1.1. Risk must be reasonable in relation to anticipated benefits and the importance of the knowledge that may be expected to result.
 - 3.2. A properly executed informed consent document will be obtained before involving a subject in a study unless a waiver is obtained.
4. This directive establishes the following responsibilities and authorities:

- 4.1. The US Air Force Surgeon General is responsible for policy and resource advocacy for the CIHUP.
- 4.2. Headquarters Air Force Medical Operations Agency (HQ AFMOA) implements the US Air Force Surgeon General's approved and directed policies.
- 4.3. The major command (MAJCOM) surgeon and MAJCOM/CC are responsible for CIHUP support and program compliance oversight for all CIHUP sites.
- 4.4. The MTF Commander and Air Force Laboratory Director are responsible for implementing the CIHUP.

5. Terms Explained:

5.1. Clinical Investigation Facility. A specialized facility within an MTF for the conduct of systematic investigations or studies designed by or with medical service personnel to develop or contribute to general medical knowledge involving humans.

5.2. Human-Use Laboratory. A specialized facility principally designed to conduct studies on advanced technology development and specialized operational support for the readiness, maintenance, protection, and extension of human capabilities in Air Force weapon systems and operations.

6. This directive implements Title 32, *Code of Federal Regulations*, Part 219, *Federal Policy for the Protection of Human Subjects*, June 18 1991; Department of Defense (DoD) Directive 6000.8, *Funding and Administration of Clinical Investigation Programs*, December 6, 1985; and DoD Directive 3216.2, *Protection of Human Subjects in DoD-Supported Research*, January 7, 1983, with Changes 1 and 2. This directive requires the collection and maintenance of information protected by the Privacy Act of 1974; Title 10, *Armed Forces*, United States Code (U.S.C.), Sections 1094, *Licensure Requirements for Healthcare Professionals*; and 1102, *Confidentiality of Medical Quality Assurance Records; Qualified Immunity for Participants*; and Title 5, *Government Organizations and Employees*, U.S.C.--in its entirety.

7. Related guidance and procedures are in AFI 40-401, *The Use of Animals in DoD Programs* (formerly AFR 169-2); AFI 40-402, *The Use of Human Subjects in Research, Development, Test, and Evaluation* (formerly AFR 169-3); and AFI 40-403, *Clinical Investigation and Human Test Subjects in the Medical Service* (formerly AFR 169-6).

8. See **Attachment 1** for measures used to comply with this policy.

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Surgeon General

Attachment 1

MEASURING AND DISPLAYING COMPLIANCE WITH POLICY

A1.1. The objective measure of overall compliance with policy is the number of completed studies resulting in presentation and or publication (Figure A1.1.). While the policy and instructions direct approval and review from within the Air Force, ultimate scientific value is determined through the presentation publication process. This process subjects the study to peer review which leads to acceptance or rejection based on the quality of study design and relevance.

A1.1.1. The number of clinical investigation studies which result in presentations and publications matched to the number of studies completed (excluding National Cancer Institute-sponsored studies). National Cancer Institute studies are excluded since these are multicenter, nationwide studies which do not give single institution publication credit.

A1.1.2. Data will be reported by local MTFs and laboratories and sent to HQ AFMOA/SGPT by 15 January through RCS: HAF-SG(A)9309, *Research Studies Resulting in Scientific Publications in Peer-Reviewed Journals*. This report is designated emergency status code C1 Continue reporting during emergency conditions, priority precedence. Submit data requirements assigned this category as prescribed, or by any means to ensure arrival on the established due date. Discontinue reporting during MINIMIZE. Measurements will be charted annually and compared against FY 92 baseline.

Figure A1.1. Sample Metric of Completed Studies Published/Presented.

