

**BY ORDER OF THE COMMANDER
59TH MEDICAL WING**

**59TH MEDICAL WING INSTRUCTION
40-401**



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Medical Command

RESEARCH MISCONDUCT

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This instruction implements AFPD 40-4, *Clinical Investigation and Human Use in Medical Research* and DoDI 3210.7, *Research Integrity and Misconduct*. This instruction outlines the responsibilities and procedures for reporting, investigating, and upward notification of allegations of misconduct in research or associated activities. This instruction is applicable to all personnel who are physically or administratively assigned to the 59th Medical Wing (MDW). This instruction does not apply to the Air National Guard or Air Force Reserve. Protected Health Information is maintained in accordance with (IAW) DoD 6025.18-R, *DoD Health Information Privacy Regulation*. Refer recommended changes and questions about this publication to the Office of Primary Responsibility using the AF Form 847, *Recommendation for Change of Publication*. The authority to waive requirements is the publication approval authority. Ensure that all records created as a result of processes prescribed in this publication are maintained IAW Air Force Manual 33-363, *Management of Records*, and disposed of IAW Air Force Records Information Management System Records Disposition Schedule.

SUMMARY OF CHANGES

This publication has been revised. This rewrite of 59 MDWI 40-401 includes: updated references and office symbols; added 59MDW/CC may designate to the Authorized Institutional Official (AIO); changed notification process to 59 MDW AIO; changed OPR.

1. Program Responsibilities.

1.1. General Overview. One mission of the 59 MDW is the performance of clinical research, a mission that directly and indirectly supports the USAF Medical Services mission and vision through world-class research towards improvements in health care. The search for new knowledge must be based on the highest principles of personal integrity and ethical standards, both in the obtaining of new data and the treatment of volunteer research participants. It is the policy of the 59 MDW to maintain the highest ethical standards in research and to investigate and resolve promptly any instances of alleged or apparent research misconduct as defined in Attachment 1.

1.2. 59 MDW Commander (59 MDW/CC). The 59MDW/CC may designate to the AIO the responsibility of the following:

1.2.1. Reviewing all allegations of perceived research misconduct.

1.2.2. Ensuring notifications are timely and appropriate to headquarters-level command and appropriate authorities as described below.

1.3. 59 MDW Scientific Investigators. Perform all research in a scientifically valid manner, with paramount consideration for protection of the volunteer research participant, and only after the research has been reviewed and approved by appropriate levels of authority; to assure all gifts are legally proffered to and accepted by 59 MDW.

1.4. 59 MDW Personnel. Any personnel can notify the 59 MDW AIO or AFLOA JACC/MLFSC (Medical Law) directly or through their supervisor/commander of any perceived or actual incident of misconduct in research.

2. Procedures.

2.1. Immediate Notification. The 59 MDW AIO will notify the Air Force Research Oversight and Compliance Division, Office of the Surgeon General, Headquarters (HQ) Research and Compliance Division (AFMSA/SGE-C) immediately in writing, with an explanation of the circumstances if:

2.1.1. The public health or safety is at risk.

2.1.2. The research institution's resources or interests are threatened or at risk.

2.1.3. Research activities are to be suspended because of the inquiry into or investigation of the allegation.

2.1.4. There is a possible violation of an instruction, ordinance, statute, regulations, code, or other civil or criminal law. Action to protect the interests of those involved in the inquiry into or investigation of the allegation is required from the parent command.

2.1.5. A premature public disclosure of the inquiry into or investigation of the allegation may compromise the process.

2.1.6. The research community or public should be informed.

2.2. Phases of the Response to an Allegation of Research Misconduct. In order of occurrence: Allegation, Inquiry, Investigation, and Adjudication. All active duty members suspected of research misconduct will be read their Article 31 rights prior to being interviewed in all phases of the response to an allegation of research misconduct. While

these phases are administrative processes, placing individuals under oath (whether for an administrative or judicial action) ensures fairness for the subject(s) of the inquiry/investigation by holding the individual(s) making the allegation and all individuals who might have information regarding the allegations to the highest standard, promoting honest testimony. Responding to questions concerning allegations of research misconduct do not trigger an active duty member's right to counsel. However, the member will be advised that active duty members are not entitled to legal counsel nor any other representation at the interview since the individual(s) will only be interviewed for the purpose of answering questions he/she chooses to answer during any phase of the process. Since Article 31 advisements vary according to the circumstances, any interviewer should contact 502 ISG/JA for advice on wording any advisement. All subjects and individuals who might have information regarding the allegations will be placed under oath prior to questioning. If an individual refuses to be placed under oath, they may still be interviewed. However, documentation of their refusal will be included in the recommendation to the 59 MDW/CC and/or AIO, who may lend less credibility to their testimony on the basis of such refusal.

2.2.1. Allegation Phase.

2.2.1.1. Notifications: In addition to the requirements of paragraph 2.1.

2.2.1.1.1. Any allegation, perceived or actual instance of research misconduct, should immediately be brought to the attention of the 59 MDW AIO preferably in writing.

2.2.1.1.2. 59 MDW AIO will immediately notify the 59 MDW Vice-Commander and 59 MDW/CC.

2.2.1.2. The 59 MDW/CC or AIO will determine whether the allegation concerns research misconduct as defined in this instruction and, as such, is subject to an inquiry. If so, the 59 MDW/CC or AIO will charge the SES chair to make recommendations for inquiry team membership consisting of a team lead and at least two (2) members from the Scientific Ethic Subcommittee (SES); 59MDW/CC will approve the inquiry team membership.

2.2.1.3. The AIO will appoint an impartial team based on SES Chair recommendations.

2.2.1.3.1. These individuals selected to review the allegation(s) and conduct the inquiry will have the appropriate expertise and have no unresolved conflicts of interest to ensure fairness of the process. Non-59 MDW SES members may be appointed if deemed necessary to preclude real or perceived conflicts of interest.

2.2.2. Inquiry Phase.

2.2.2.1. Notifications: In addition to the requirements of paragraph 2.1.

2.2.2.1.1. The SES is charged with the responsibility of promptly initiating an impartial inquiry into any alleged misconduct and making recommendations to the 59 MDW/CC or AIO regarding their findings. The inquiry must be completed and the 59 MDW/CC or AIO notified of the results of the inquiry within 60 calendar days unless circumstances warrant a longer period. The notification will be in the form of an official written report which details the evidence reviewed,

summarizes relevant interviews including any comments made by the individual(s) accused (all interviews should be conducted as noted in 2.2), and presents the conclusions of the inquiry and relevant recommendations. A recommendation to proceed to the investigation stage should be based on probable cause to believe that research misconduct has occurred.

2.2.2.1.2. The inquiry team will collect, document and maintain findings.

2.2.2.1.3. Before the inquiry begins, the SES will send a written notification to the individual(s) against whom the allegations have been made. This notification will detail the allegation(s) against the subject(s), notify the subject(s) that an inquiry team has been initiated by 59 MDW/CC or AIO, inform the subject(s) that they will be sent the SES' official written report 10 calendar days prior to it being sent to 59 MDW/CC or AIO, and assuring the subject(s) that he/she will be given 10 calendar days from the date the written recommendation was sent to provide his/her own written response that will become part of the record for 59 MDW/CC to review.

2.2.2.2. If the inquiry takes longer than 60 days to complete, the record of the inquiry shall include documentation of the reasons for exceeding the 60-day period.

2.2.2.3. Detailed documentation of an inquiry to permit a later assessment of the reasons that an investigation was or was not warranted will be maintained in a secure manner for at least three (3) years after termination of the inquiry.

2.2.2.4. The following documents are related to an allegation of research misconduct:

2.2.2.4.1. Written statement of the original allegation;

2.2.2.4.2. Formal notification to the subject of the allegation;

2.2.2.4.3. Written outcome of the inquiry phase and supporting documentation;

2.2.2.4.4. Written report of the investigation, including the evidentiary record and supporting documentation; and

2.2.2.4.5. If applicable, statement of recommended corrective actions and any response thereto, including any corrective action plan.

2.2.2.4.6. The SES chair will maintain the inquiry team's documentation and provide an "information only" update to the Scientific Advisory Committee (SAC).

2.2.3. Investigation Phase.

2.2.3.1. Notifications: In addition to the requirements of paragraph 2.1.

2.2.3.1.1. If, based on the initial inquiry, the 59 MDW/CC or AIO determines that an official investigation is warranted, HQ AFMSA/SGEC, will be notified in writing on or before the date the investigation begins.

2.2.3.1.2. Research institutions will notify the funding agency (or agencies) of an allegation of research misconduct if (1) the allegation involves federally funded research (or an application for federal funding) and meets the federal definition of research (see glossary of references and supporting information), and (2) if the

institution's inquiry into the allegation determines there is sufficient evidence to proceed to an investigation. If the investigation involves Department of Health and Human Services (e.g., National Institutes of Health) or National Cancer Institute grant funds, the Director of the Public Health Service's Office of Research Integrity (PHS/ORI) will be notified.

2.2.3.2. If the findings so warrant, the 59 MDW/CC or AIO will order a formal investigation by the appointed "investigative team" within 30 days of the completion of the inquiry. The investigation normally will include examination of all documentation, including but not necessarily limited to relevant research data and proposals, publications, correspondence, and memoranda of telephone calls. Whenever possible, interviews should be conducted of all individuals involved either in making the allegation or against whom the allegation is made, as well as other individuals who might have information regarding key aspects of the allegations; complete summaries of these interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file. This investigation will normally be completed and a formal written report presented to the 59 MDW/CC within 90 days. (Requirements for retention of records are identified in the beginning paragraph of this instruction.)

2.2.3.2.1. The appointed investigative team will report their recommendations thru the SES Chair to the AIO who reports findings to 59 MDW/CC and others as needed.

2.2.3.2.2. The SES chair will maintain the investigative team's documentation and provide an "information only" update to the SAC.

2.2.3.2.2.1. Before the formal investigation begins, the SES will send a written notification to the individual(s) against whom the allegations have been made. This notification will detail the allegation(s) against the subject(s), notify the subject(s) that an investigation has been initiated by 59 MDW/CC, and inform the subject(s) that they have 7 calendar days to request the opportunity to be interviewed by the SES under oath prior to the completion of the investigation.

2.2.3.3. A finding of research misconduct requires that:

2.2.3.3.1. There be a significant departure from accepted practices of the relevant research community; and

2.2.3.3.2. The misconduct be committed intentionally, or knowingly, or recklessly; and

2.2.3.3.3. The allegation is proven by a preponderance of evidence.

2.2.3.3.4. Regarding allegations that a civil or criminal statute was violated, it is presumed that any violation of a criminal or civil statute constitutes a significant departure from accepted practices of the relevant research community if the violation is proven by a preponderance of the evidence to have been committed intentionally.

2.2.4. Adjudication Phase. Notifications: In addition to the requirements of paragraph 2.1, interim and final documentation will be made available to AFMSA/SGE-C or Director, PHS/ORI as applicable. When an investigation is complete, the research institution will forward to the agency a copy of the evidentiary record, the investigative report, and recommendations made to the institution's adjudicating official, and the subject's written response to the recommendations (if any). When a research institution completes the adjudication phase, it will forward the adjudicating official's decision and notify the agency of any corrective actions taken or planned. Applicable notification should also be made within 24 hours of obtaining a reasonable indication of possible criminal violations.

2.2.4.1. Interim administrative actions, as appropriate, will be undertaken by 59 MDW/CC to protect any federal funds involved and to ensure that the purposes of the financial assistance are being carried out.

2.2.4.2. Appropriate sanctions or disciplinary actions, based on the degree of severity of the misconduct, will be imposed by the 59 MDW/CC. In deciding what administrative actions are appropriate, the agency should consider the seriousness of the misconduct, including, but not limited to, the degree to which the misconduct was knowing, intentional, or reckless, was an isolated event or part of a pattern, or had significant impact on the research record, research subjects, other researchers, institutions, or the public welfare.

2.2.4.3. Possible Administrative Actions. Administrative actions available include, but are not limited to, appropriate steps to correct the research record, letters of admonishment, the imposition of special certification or assurance requirements to ensure compliance with applicable regulations or terms of an award; suspension or termination of an active award; or suspension and debarment in accordance with applicable government-wide rules on suspension and debarment. In the event of suspension or debarment, the information is made publicly available through the List of Parties Excluded from Federal Procurement and Non-Procurement Programs maintained by the U.S. General Services Administration. With respect to administrative actions imposed on government employees, the agencies must comply with all relevant federal personnel policies and laws.

2.2.4.4. In Case of Criminal or Civil Fraud Violations. If the funding agency believes that criminal or civil fraud violations may have occurred, the agency shall promptly refer the matter to the Department of Justice, the Inspector General for the agency, or other appropriate investigative body.

2.2.5. Separation of Phases. Adjudication is separated organizationally from inquiry and investigation. Likewise, appeals are separated organizationally from inquiry and investigation.

2.3. Safeguards.

2.3.1. Diligent efforts, as appropriate, will be undertaken to restore the reputations of persons alleged to have engaged in misconduct when the allegations are not confirmed, and to protect the positions and reputations of those persons, who in good faith, make allegations.

2.3.2. The privacy of those who in good faith report apparent misconduct will be protected to the maximum extent possible. Safeguards include protection against retaliation for informants who make good faith allegations, fair and objective procedures for examination and resolution of allegations of research misconduct, and diligence for protecting the positions and reputations of those persons who make allegations of research misconduct in good faith.

2.3.3. The affected individual(s) will be afforded confidential treatment, a prompt and thorough investigation, and the opportunity to comment on all allegations and findings of the inquiry or investigation. The mere filing of an allegation of research misconduct against an individual will not bring their research to a halt or be the basis for other disciplinary or adverse action absent other compelling reasons. Other safeguards include the timely written notification of subject(s) regarding substantive allegations made against them; a description of all such allegations; reasonable access to the data and other evidence supporting the allegations; and the opportunity to respond to all allegations, the supporting evidence and proposed findings of research misconduct (if any).

2.3.4. To the extent possible consistent with a fair and thorough investigation and as allowed by law, knowledge about the identity of subject(s) and informant(s) is limited to those who need to know. Records maintained by the agency during the course of responding to an allegation of research misconduct are exempt from disclosure under the Freedom of Information Act to the extent permitted by law and regulation.

2.3.5. These four phases taken in response to an allegation of research misconduct are administrative procedures independent of any judicial action under the Uniform Code of Military Justice (UCMJ). Nothing in this instruction will impair the independent investigation of a member for UCMJ judicial action (e.g., investigation/initiation of a court-martial). Therefore, 59 MDW/CC may contact 502 ISG/JA when research misconduct has been deemed serious enough to warrant UCMJ judicial action. In addition, any member representing the Air Force's interests during the four phases may contact 59 MDW/JA for interpretive guidance on this instruction or 502 ISG/JA regarding UCMJ issues.

JOSEPH R RICHARDS, Colonel, MC
Chief of the Medical Staff

Attachment 1**GLOSSARY OF REFERENCES AND SUPPORTING INFORMATION*****References***

42 Code of Federal Regulations Part 93, *Research Misconduct*, 3 May 2016

AFI 51-601, *Gifts to the Department of the Air Force*, 26 November 2003

AFPD 40-4, *Clinical Investigation and Human Use in Medical Research*, 11 May 1994

DoD Directive 5500.7, *Standards of Conduct*, 29 November 2007

DoDI 3210.7, *Research Integrity and Misconduct*, 14 May 2004

DoDI 3216.02, *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research*, 8 November 2011

DoDI 3216.02_AFI 40-402, *Protection of Human Subject and Adherence to Ethical Standards in Air Force Supported Research*, 10 September 2014

Adopted Form

AF Form 847, *Recommendation for Change of Publication*

Abbreviations and Acronyms

AFMSA/SGE-C—Research and Compliance Division, Office of the Surgeon General

AIO—Authorized Institutional Official

HQ—Headquarters

IAW—In Accordance With

JA—Medical Law

MDW—Medical Wing

PHS/ORI—Director of the Public Health Service's Office of Research Integrity

SAC—Scientific Advisory Committee

SES—Scientific Ethic Subcommittee

UCMJ—Uniform Code of Military Justice

Terms

Adjudication—When recommendations are reviewed and appropriate corrective actions are determined.

Allegation—An unsupported assertion that misconduct has taken place. The determination as to whether the allegation concerns research misconduct as defined in this instruction and as such is subject to an inquiry has yet to be established by the 59 MDW/CC or AIO.

Fabrication—Making up data or results and recording or reporting them.

Falsification—Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Inquiry—Discovery and interpretation of facts surrounding an allegation of research misconduct to provide recommendation to 59 MDW/CC or designee as to whether an investigation is warranted.

Investigation—The formal development of a factual record, and the examination of that record leading to recommendation of dismissal of the case or to a recommendation for a finding of research misconduct or other appropriate recommendation for resolution of the allegation.

Phases of the Response to an Allegation of Research Misconduct—In order of occurrence: Allegation, Inquiry, Investigation, and Adjudication.

Plagiarism—The appropriation of another person's ideas, processes, results or words without giving appropriate credit.

Research—As used in this instruction includes all basic, applied, and demonstration research in all fields of science, engineering, and mathematics. This includes, but is not limited to, research in economics, education, linguistics, medicine, psychology, social sciences, statistics, and research involving human subjects or records.

Research Misconduct—Fabrication, falsification, plagiarism or other practices that intentionally, knowingly or recklessly represents a significant departure from accepted practices of the relevant research community, for proposing, performing, or reviewing research or in reporting research results. Research misconduct does not include an honest error or difference in opinion, interpretation or judgment concerning data.

Research Record—The record of data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.