U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION

National Policy

ORDER 9500.25C

Effective date:
02/15/2022

SUBJ: Protection of Human Research Subjects

1. Purpose of This Order. This order standardizes policies and procedures for conducting research involving human test subjects and promulgates the "Common Rule." Federal policy for the protection of human subjects in research conducted by the Federal Aviation Administration (FAA). This order establishes the FAA Institutional Review Board (IRB).

2. Audience. This order is distributed to organizations that must comply with its requirements, which include the Office of Aerospace Medicine (AAM), FAA Technical Center (ANG-E), Flight Standards Flight Technologies and Procedures Division (AFS-400), Headquarters Human Factors Division (ANG-C1), and any organization conducting human subjects research as defined by Title 49 *Code of Federal Regulations* (CFR) part 11.101.

3. Where Can I Find This Order? This order is available on the FAA Orders & Notices website at https://employees.faa.gov/tools_resources/orders_notices/ and available to the public at http://www.faa.gov/regulations_policies/orders_notices/.

4. What this order cancels. This order cancels FAA Order 9500.25B Protection of Human Research Subjects, dated October 8, 2019.

5. Explanation of Policy Changes. This order is revised to clarify the FAA's procedures with regard to the selection of a reviewing IRB in contracts, grants, Cooperative Research and Development Agreements (CRADAs), and other agreements where human research is contemplated as well as to correct a typographical error. Amendments are herein made to 6a - Assurance, 8b - Contracts, Grants, and Other Agreements, 9d, and 18g - Review and Extensions. Appendix A has been added for reference.

6. Background. In December 1981, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (the Commission) issued a report, which included a recommendation that Federal agencies engaged in research involving human subjects adopt the pertinent regulations of the Department of Health and Human Services (DHHS). These regulations, specified in 45 CFR part 46, deal with requirements for the protection of human research subjects. In response to the Commission's recommendation, in March 1982, the Chairman of the Federal Coordination Council for Science, Engineering, and Technology appointed an Ad Hoc Committee for the Protection of Human Research Subjects. The Ad Hoc Committee, composed of representatives of affected departments and agencies, developed a Model Policy, which applies to research involving human subjects that is conducted, supported, or regulated by Federal departments and agencies. This policy is based on Subpart A of 45 CFR part 46. On January 8, 1984, the Secretary of Transportation agreed to implement the Model Policy without exception. The final form

of this Model Policy was promulgated on June 18, 1991. Title 45 CFR part 46 was updated effective January 21, 2019, and revisions to 49 CFR part 11 implemented these changes for Department of Transportation agencies. This order specifies procedures that are in accordance with the revised Common Rule. Subsequent to the promulgation of the Model Policy, the Office of the Secretary of Transportation identified the Office of Aerospace Medicine as the DOT representative on the Interagency Human Subjects Coordinating Committee. This order, dealing with the FAA program for the protection of human research subjects, follows from that responsibility.

7. Definitions.

a. Assurance (Multiple Projects or Single Project) **-** written documentation, satisfactory to the Administrator, required from the prospective performing institution that ensures institutional compliance with and implementation of appropriate procedures for the protection of human research subjects. At a minimum, this should comprise the institution's valid IRB registration and Federalwide Assurance (FWA) numbers.

b. Certification - official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

c. Contracting Officer - a person authorized to enter into, administer, or terminate contracts and to make related determinations and findings.

d. Exempt Review - review procedure carried out by the IRB chairperson to determine whether a proposal is exempt from review under 49 CFR part 11. Researchers may not make this determination themselves but must submit a proposal stating how the research meets the criteria for exemption, referencing 49 CFR part 11. See section 19a below.

e. Expedited Review - review procedure carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. Only those research proposals, which involve no more than minimal risk may utilize this review process. See section 19b below.

f. Human Subject - living individual about whom an investigator (whether professional or student) conducting research obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, and analyzes or generates identifiable private information or identifiable biospecimens. Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the

investigator or associated with the information. An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

This definition under 49 CFR part 11 does not apply to information (data and/or specimens) collected solely from deceased persons. However, the Health Insurance Portability and Accountability Act (HIPAA) of 1996 protects individually identifiable health information for 50 years following the date of death of an individual. Title 45 CFR part 164 defines how such information may be used for research. See Section 11 for FAA Policy to comply with those requirements.

g. Institution - any public or private entity, or department or agency (including Federal, state, and other agencies).

h. Institutional Review Board (IRB) - established in accord with and for the purposes expressed in this policy.

i. IRB approval - determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

j. Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, *legally authorized representative* means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

k. Minimal risk - probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

l. Public health authority - agency or authority of the United States, a state, territory, or political subdivision of a state or territory, an Indian tribe, foreign government, person or entity acting under a grant of authority or contract with such public agency. Includes the employees or agents of such public agency or its contractors, persons, or entities to whom it has granted authority that is responsible for public health matters as part of its official mandate.

m. Research - systemic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities meeting this definition are defined in further detail in 49 CFR part 11.102(l).

8. Policy. It is the policy of FAA to ensure the safety and well-being of all human subjects taking part in FAA-sponsored or FAA-conducted scientific research, and to adhere strictly to the provisions of 49 CFR part 11.

9. Scope. This order applies to all research involving humans as test subjects (including obtaining biospecimens through intervention, interaction with an individual, or analysis of biospecimens) conducted by the FAA, by or under the direct supervision of an FAA employee, or an employee detailed to the FAA from industry, a university or from another Government agency. This also applies to all contractors and subcontractors performing work for FAA as provided by law and/or contract, and as implemented by the appropriate contracting officer.

a. International Studies. All studies conducted outside the United States involving human subjects under FAA grant, contract, or other agreement will be reviewed by the FAA IRB. Human subjects outside of the United States who participate in research conducted or funded by the FAA must receive an equal level of protection as research participants inside the United States.

b. Contracts, Grants, and Other Agreements.

i. Inclusion of IRB Clause. In all contracts, grants, CRADAs, and other agreements where human research is contemplated, the Contracting or Grants Officer (or Technology Transfer Program Manager (ORTA) in the instance of CRADAs) must ensure that an appropriate standard clause or other language is incorporated that requires compliance with the procedures of this order.

ii. Selection of Reviewing IRB. The FAA IRB will determine the reviewing IRB in accordance with 49 CFR §11.114. More particularly:

(1) No FAA Substantial Involvement in Activities, Work, Effort. Where the human research involves no substantial involvement on the part of the FAA, the FAA Contracting Officer, Grants Officer, or Technology Transfer Program Manager must ensure that the FAA has received from the institution its valid, appropriate Assurance(s). If the FAA Contracting or Grants Officer has confirmed that the institution has submitted the appropriate Assurance(s), the FAA IRB will accept the findings of the institution's IRB and will conduct no further IRB review.

(2) FAA Substantial Involvement in Activities, Work, Effort. Where the human research involves substantial involvement on the part of the FAA, the FAA Contracting Officer, Grants Officer, or Technology Transfer Program Manager must submit to the FAA IRB:

(a) The institution's valid, appropriate Assurance(s);

(b) A copy of the statement of work (SOW), performance work statement (PWS), or similar work statement setting forth the details regarding the FAA's participation in the research and description of the level of FAA involvement;

(c) A copy of the institution's complete IRB protocol; and,

(d) Any statements from the institution clarifying, revising, or amending the protocol.

After review and consideration of (2) (a)-(d), the FAA IRB will determine whether FAA employees and/or support contractors are involved in human testing:

(e) If FAA employees and/or support contractors will be involved in human testing, the FAA IRB will be determined to be the reviewing IRB;

(f) If FAA employees and/or support contractors will not be involved in human testing, the FAA IRB will send a designation letter in accordance with Appendix A hereto, a copy of which will be kept with the contract, grant, CRADA, or other agreement file.

(3) Any substantive modification of the SOW, PWS, or similar work statement that modifies the FAA's participation in the research and/or description of the level of FAA involvement in conducting the activities, work, or effort must be resubmitted through the above process.

10. Responsibilities and Authorities.

a. The Administrator establishes the FAA policy for the protection of human subjects consistent with 49 CFR part 11.

b. The Federal Air Surgeon (AAM-1) is responsible for the implementation of 49 CFR part 11 within the FAA in accordance with the policy established by the Administrator.

c. Principal Investigators of any research projects involving human subjects are responsible for ensuring that the protections afforded subjects under 49 CFR part 11 are maintained and that all proposed research falling within the scope of this order is submitted for review as described herein.

d. Contracting Officers, Grant Officers, and the Technology Transfer Program Manager (ORTA) are responsible for the inclusion of appropriate language in all research projects falling within the scope of this order, which will ensure that all FAA research activities involving human subjects are conducted in accordance with 49 CFR part 11. They must also ensure that performing organizations have completed appropriate Assurances, in accordance with 49 CFR part 11.103.

11. FAA Institutional Review Board. A committee composed of at least five persons will be constituted to evaluate matters within the scope of this order. The committee is called the FAA IRB and is empowered to review all research conducted by the FAA, which falls within the scope of this order. This IRB represents the Federal Air Surgeon and must approve all research having FAA involvement judged to contain above minimal human subject risk. With the approval of the Federal Air Surgeon, other IRBs may be constituted by individual offices within the FAA to review research falling within their particular domain. The membership and actions of these other boards will be subject to the review and approval of the Federal Air Surgeon.

Research involving only information (data and/or specimens) collected from deceased persons is not subject to 49 CFR part 11, but must comply with HIPAA and 45 CFR part 164. The FAA is a Public Health Authority under HIPAA. The Federal Air Surgeon designates the IRB to review proposals for decedent research. Researchers must submit a description of the research and attestations that the proposal is solely for research on the protected health information (PHI; data and/or specimens) of decedents, that the researcher has access to documentation of the death of such individuals, that the PHI sought is necessary to research purposes, and that readily-ascertainable individually identifiable information will not be released through any products of the research. The IRB will receive researcher descriptions and issue a waiver of consent for deceased individuals.

Research involving both living and deceased individuals is subject to IRB review and waiver of consent for deceased individuals.

12. Composition of the FAA IRB. The FAA IRB consists of at least five members appointed by the Federal Air Surgeon or her/his designee. The chair of the FAA IRB and members are appointed for one-year terms. Additional members, beyond the minimum, may be appointed by the Federal Air Surgeon. In order to comply with the requirements of the Federal Advisory Committee Act (Public Law 92-463, Title 5, U.S. Code, Appendix II), all members of the IRB must be Federal employees or under contract to FAA. This requirement also applies to the ad hoc members. The membership of the IRB must be diverse, with, at a minimum, the following members:

a. One member who is a physician with clinical experience or specialization in aerospace medicine.

b. One member with expertise in the behavioral and social sciences, which is defined as meeting qualifications at the managerial level for positions classified by the Office of Personnel Management as Social Sciences (includes Political Science), Psychology, Sociology, Anthropology, and Statistics (provided experiences emphasize social science applications).

c. One member who is not an employee of the FAA, with expertise in ethics, which is one whose judgment on ethics and ethical codes has come to be trusted by a specific community. This member, if not an employee of another Federal Agency, must be under contract to FAA in order to comply with the Federal Advisory Committee Act, as noted above.

d. One member with expertise in safety or industrial hygiene. In addition to a review of research protocols, this member will, at the direction of the IRB Chair, conduct on-site inspections to assess the overall safety of the proposed research projects.

e. One member representing the FAA Chief Counsel.

13. Ad hoc members of the FAA IRB. If members of a group at special risk (See Section 20) are included in a proposed project, an expert familiar with that particular group will be included as an ad hoc member of the IRB. Ad hoc members may also be appointed to provide special expertise related to a proposed project under review. Ad hoc members are appointed by the FAA IRB Chair for specific project reviews and do not take part in discussions or vote on projects beyond the specific project for which their expertise was required.

14. Prohibitions against conflicts of interest.

a. Scientific Conflict of Interest. Members of the IRB whose projects are under review will recuse themselves from voting but may, at the discretion of the IRB Chair, participate in discussions. This prohibition also applies to supervisors and other managers of scientists whose research projects are under review. Scientists whose research projects are under review are specifically excluded from ad hoc membership.

b. Financial Conflict of Interest. No member of the IRB will participate in IRB proceedings

concerning a project in which the member, the member's immediate family, employer, or partner, or an organization in which the member serves as officer, director, or trustee or an organization with whom the member is negotiating or has any arrangement concerning prospective employment, has a financial interest without a written waiver issued by the IRB Chair, with the concurrence of the Chief Counsel's IRB representative. This is to comply with 49 CFR part 11.

15. Frequency of Meetings. Meetings will be called as determined by the IRB Chair to meet review needs. Meetings will also be called by the IRB Chair as necessary to consider unprogrammed research, changes in approved protocols, or petitions for waivers.

16. Determination of Requirement for IRB Review. 49 CFR part 11.101 will be used to determine whether a planned activity is covered by provisions of this policy. FAA personnel may determine from these definitions that an activity is *not research*, but may not determine that a research activity is *exempt* (see section 19.a. below). Any questions about this determination should be directed to the IRB chairperson. Title 49 CFR part 11.101(c) defers judgment as to whether an activity is covered by the common rule to the agency head.

17. Application for Review. The senior task scientist (principal investigator) performing any research as described in this order must submit a research application to the IRB in a format to be provided by the IRB Chair. Each application will include an attestation of compliance with Federal regulations for the protection of human research subjects utilizing a format designated by the IRB. This or a related document will be utilized to document compliance with the "Common Rule" policy on human research subjects. Each application must include all elements listed in paragraph 18, research protocol.

18. Research protocol. The protocol submitted with the Research Application will always include at least the following information:

a. Subject characteristics, including both numbers and types of subjects.

b. Use of any additionally protected groups, as specified in paragraph 20.

c. Provisions to ensure privacy and confidentiality of subject data.

d. Ethical considerations, including assessment of physical risk, safety precautions, and provisions for medical assistance.

e. Informed consent, including a copy of the consent document to be used.

f. An explanation of why this project qualifies for exempt or expedited review, if appropriate.

19. IRB Review Process and Criteria:

a. Exempt Review. Research that meets the specifications of 49 CFR part 11.104 is exempt from IRB review and is not subject to further review under this order. Researchers may not make this determination themselves, but must submit a proposal stating how the research meets the criteria for

exemption. The chairperson may determine that Exempt Review is not appropriate for a proposal and require its submission for Expedited or full review, but may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited review procedures as set forth in 49 CFR part 11, and further specified in this order.

b. Expedited Review. If the Chair of the IRB judges a research proposal to meet the specifications of 49 CFR part 11.110, involving no more than minimal risk or review of minor changes in previously approved research, an expedited review process may be used. A review of research found to qualify for expedited review may be carried out by the IRB Chair.

c. Full Board Review. Members of the IRB will be provided copies of experiment protocols requiring evaluation no later than 30 calendar days prior to the IRB meeting dates set by the chair. The IRB Chair will retain the prerogative of recommending exceptions, expeditious reviews, and interim approval pending either routine notification of IRB members or the reconvening of the full IRB.

d. Criteria for IRB approval. The IRB will review and approve, request changes, or disapprove Research Applications in accordance with 49 CFR part 11.111. The IRB must determine that all of the following requirements are satisfied:

i. Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.

ii. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.

iii. Selection of subjects is equitable.

iv. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 49 CFR part 11.116.

v. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

vi. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

e. Review of FAA IRB Findings. The Federal Air Surgeon or his designee will be provided with minutes of IRB deliberations and decisions. While expressed review and concurrence is desirable, if the Federal Air Surgeon does not indicate any objections prior to experiment startup dates, this will be considered concurrence with the IRB recommendation.

f. Review of Local IRB Findings. If a local FAA IRB (for example, an IRB approved by the Federal Air Surgeon to review research at the Technical Center) determines the risks associated with a proposed research project are greater than minimal, then the local FAA IRB will refer the Research Application to the FAA IRB. Research must not commence until the FAA IRB representing the

Federal Air Surgeon provides approval.

g. Review and Extensions. Continuing review of research protocols is required for protocols deemed by the IRB to present more than minimal risk. The IRB will implement this requirement by approving these protocols for a period not to exceed one year. Review is initiated when the Principal Investigator makes an application for extension. Approved protocols that have progressed to the point to only involve data analysis, including analysis of identifiable private information or biospecimens, do not require renewal and review.

h. Amendments. Modifications to an approved protocol require prior approval of the IRB Chair. Principal Investigators request approval by submitting an Amendment application.

20. Special Classes of Subjects. Research involving subjects vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, requires assessment of the risks involved and the degree to which informed, voluntary consent to participate has been obtained. At a minimum, when considering research involving members of these or similar groups, the IRB must incorporate members possessing special expertise with the subject group and require evidence from the investigator that due consideration has been given to the use of other classes of subjects. As specified in 49 CFR part 11, these groups specifically include:

a. Pregnant women, human fetuses, and neonates

b. Prisoners

c. Children

21. Recordkeeping. The IRB will maintain the following records for three years following protocol completion:

a. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects.

b. Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

c. Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review.

d. Copies of all correspondence between the IRB and the investigators that records a formal transaction or decision (e.g., letters of memorandum documenting approval or IRB application).

e. A list of IRB members.

f. Written procedures for the IRB.

g. Statements of significant new findings provided to subjects.

h. The rationale for a reviewer's determination that research otherwise eligible for expedited approval is more than a minimal risk.

i. Principal Investigators will maintain copies of signed consent forms for a period of three years following completion of the research. An exception will be made in research where the Principal Investigator does not have access to the consent forms for protection of subjects' privacy, purposes of conducting blinded research, or off-site work as performed via a Contract. In such cases, the IRB may determine retention requirements for signed consent forms.

22. Requests for Information. Additional information on the requirements of this order may be obtained from the Chair, Institutional Review Board (AAM-3A).

23. Distribution. This order is distributed electronically to the branch level in AAM, to the division level at the FAA Technical Center (ANG-E), and Director level in the Human Factors Division (ANG-Cl). It is also available to the public via the FAA order and notices internet website.

Steve Dickson
Administrator

APPENDIX A

U.S. Department
of Transportation
**Federal Aviation
Administration**

Civil Aerospace Medical Institute
AAM-3A
6500 MacArthur Blvd.
Oklahoma City, OK 73169

[*DATE*]

[*INSTITUTION CONTACT NAME/ADDRESS*]

Dear _____,

Per 49 Code of Federal Regulations Part 11 (Protection of Human Subjects), Section 11.114 (Cooperative Research), "Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research."

I have reviewed [*Contract/Grant/CRADA/Agreement No.*], for [*name of proposed research work*] awarded to [*institution name*] and your request that [*name of requested reviewing IRB*] serve as the reviewing IRB. Because your personnel will be working directly with the participating human research subject in your facilities, I concur with your request and designate [*name of requested reviewing IRB*] as the reviewing IRB. In doing so, I have reviewed your IRB Registration and Federalwide Assurance Documents posted with the Department of Human Services Office for Human Research Protections and found all to be current and active.

Please provide a copy of all approved protocols and amendments for work under this contract to me at the above address.

Sincerely,

Thomas R. Chidester, Ph.D.
Chair, Institutional Review Board