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AIR FORCE RESEARCH LABORATORY
(AFRL)

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Scientific/Research and Development

AFRL TEST ACTIVITY INVOLVING HUMAN PARTICIPANTS

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This publication implements AFPD61-1, *Management of Science and Technology*; AFRL Instructions (AFRLI) 40-402, *Protection of Human Subjects in Research,* and 61-103, *AFRL Research Test Management*. This instruction provides guidance for review and approval of test activity involving humans (subjects and participants). The intent of this instruction is to ensure Air Force Research Laboratory (AFRL) researchers and organizations conducting test activity include appropriate reviews and documentation, assuring that risk for human involvement is minimized. In the event the activity constitutes human subject research, such activity is referred for proper further review as defined by AFRLI 40-402. All applicable civilian personnel policies, instructions, and bargaining agreements will apply. This publication may be supplemented at any level, but all direct Supplements must be routed to the Office of Primary Responsibility (OPR) of this publication for coordination prior to certification and approval. Refer recommended changes and questions about this publication to the Office of Primary Responsibility (OPR) using the AF Form 847, *Recommendation for Change of Publication*; route AF Form 847 from the field through the appropriate functional manager's chain of command. Ensure all records created as a result of processes prescribed in this publication are maintained in accordance with (IAW) Air Force Instruction (AFI) 33-322, *Records Management and Information Governance Program* and disposed of in accordance with Air Force Records Information Management Systems (AFRIMS) Records Disposition Schedule (RDS).

SUMMARY OF CHANGES

This publication has been revised and must be completely reviewed. Changes to the document include the OPR, certifying official, as well as waiver authorities. Reference documents and their use in the research test process were also updated to the most current versions.

1. Purpose and Scope.

1.1. Purpose. The purpose of this instruction is to provide safeguards to enhance human participant and human subject safety in the conduct of research test, evaluation and demonstration activities and to ensure compliance with human research protections IAW AFRLI 40-402 *Protection of Human Subjects in Research*. Approval to proceed with human subject testing is provided by the IRB as applicable in addition to other required approvals such as those mandated by the parent to this volume and AFI 91-202 *The US Air Force Mishap Prevention Program* as supplemented. This instruction provides guidance for obtaining additional reviews as required to meet the purpose stated above.

1.2. Scope. The guidance contained in this instruction applies to all AFRL test activities involving human participants/subjects, including experiments and demonstrations that involve AFRL assets (full or part ownership) or AFRL personnel (government, military, and contractors), or where AFRL either holds mishap accountability or some level of liability. This guidance also applies to all tests executed by organizations under contract to AFRL where AFRL holds either mishap accountability or some level of liability.

1.2.1. Test activities involving humans are defined as those activities which involve an interaction or intervention with an individual. For example, an intervention can involve physical procedures or a manipulation of the individual's environment. An interaction can include such activities as operation of an electromechanical system, medical procedures, psychological testing, surveys, interviews, and focus groups. Please refer to the *Terms* section for further distinction between human participants and human subjects, but a simple characterization is that human participants are not themselves the system under test, but human subjects are.

1.3. Waivers. Coordinate waiver requests with local Technology Directorate (TD) test leads for coordination/staffing to the 711 HPW Chief Engineer (711 HPW/EN). The 711 HPW/EN will in turn coordinate waivers with AFRL Plans and Programs (AFRL/XP) and AFRL Safety Office (AFRL/SE) as required.

2. Roles and Responsibilities.

2.1. AFRL Site/Detachment Safety Personnel will:

2.1.1. Assist the PM in developing the safety component of the test plan and help assess if the activity constitutes human test participant or human subject research. The Human Subject Worksheet (**Attachment 2**) should be used to aid in making this assessment. This worksheet is to be accomplished digitally through the AFRL Enterprise Business System (EBS) and is included here as a reference or as a backup method. If the activity does constitute human subject research, it must be reviewed by the AFRL Institutional Review Board (IRB) (see AFRLI 40-402). If in doubt, refer the matter to the AFRL IRB for an official and final determination. Only approved staff of the AFRL IRB is authorized to make official human subjects research determinations.

2.1.2. Undergo annual human subjects research training provided by the AFRL IRB. Such training will equip the trainee with the knowledge needed to identify when a test plan needs to be submitted to the AFRL IRB for a human subject research determination or whether or not a test plan constitutes test activity involving human participants. If a test activity involves human participants, it is subject to the relevant stipulations found elsewhere in this Volume (i.e., those found in Pars. 3.1-3.3 and **Attachment 3**).

2.1.3. Confirm their own AFRL IRB training date is within one year prior to accomplishing The Human Subject Worksheet (**Attachment 2**). Contact the AFRL IRB to re-accomplish training if older than one year.

2.2. PM will:

2.2.1. Contact the AFRL Site/Detachment Safety Office and Directorate/Wing Test Lead early in the program development and activity planning stage and provide information concerning test requirements. The PM is responsible for developing a test plan and coordinating that plan with the AFRL Site/Detachment Safety Office and Directorate/Wing Test Lead.

2.2.2. Ensure timely compliance with all applicable requirements and be solely responsible for the planning and execution of the test activity. The PM plans, conducts, manages and documents the activity in accordance with AFI 91-202 as supplemented; AFRLI 61-103; and with this instruction.

2.2.3. Submit test plans to AFRL IRB for official research determination when needed, or when provisions of AFI 99-103, Section 6.4.5 apply to the test activity.

2.3. Test Execution Authority (TEA) will:

2.3.1. Accept the residual safety risk as assessed by the safety review process.

2.3.2. Undergo training provided by the AFRL IRB prior to approving a test activity involving human subject research. Such training will equip the TEA with the knowledge needed to understand any stipulations levied by the IRB on a test activity involving human subject research.

2.3.3. If the TEA has an AFRL IRB training date within one year prior to accomplishing TEA responsibilities for a test plan, such training need not be repeated. Contact the AFRL IRB to re-accomplish training if older than one year.

2.4. AFRL IRB will:

2.4.1. Provide annual human subjects research training to AFRL safety personnel when contacted by the Site/Detachment Safety Office.

2.4.2. Provide annual human subjects research training to TEA when contacted by the TEA.

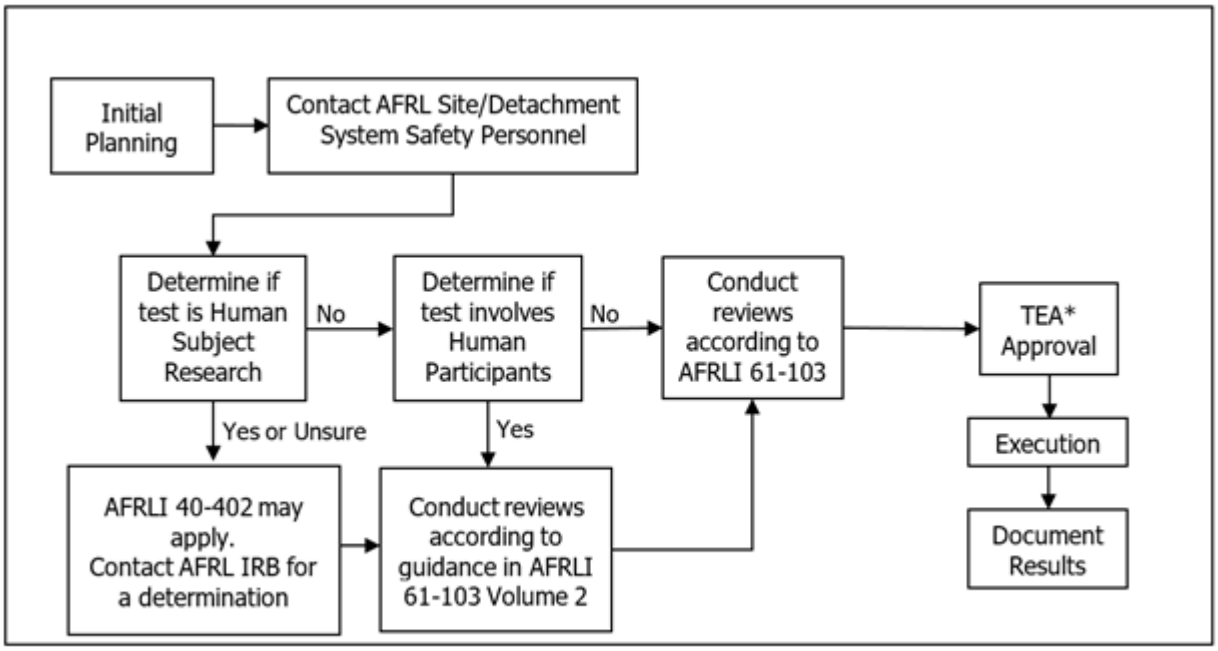
3. Test Process.

3.1. AFRL Test Activity. All AFRL test activity which potentially involves human participants or human subjects will follow the determination and review process as depicted in **Figure 1** When test activities include human subjects or human participants, items related to their participation must be listed in the test plan as described in **Attachment 3**. IAW 91-202 AFRL Supplement all test plans must be coordinated with the appropriate AFRL Site/Detachment Safety Office prior to conducting any tests with human participants and the AFRL IRB if involving human subjects.

3.2. Testing. The test should be conducted in such a way as to avoid any mental or physical harm or unnecessary discomfort to participants. The test plan must detail the safety aspects taken into account for the test. During the course of the test, the PM, scientist, or engineer in charge must be prepared to terminate the test at any stage, if he or she has any cause to believe, in the exercise of good faith, superior skill and careful judgment that continuation of the test is likely to result in injury, disability, or death to the participant, or is unlikely to produce the expected outcome through technical, Operational Risk Management (ORM), safety, or other analysis method. No individual under the age of 18 will be a test participant. Test participants must voluntarily consent to being a test participant. Any individual unable to provide consent will not be used as a test participant.

3.3. Human Participant Data. All information about a human test participant will be maintained consistent with existing Privacy Act and Department of Defense Privacy Rules, and in accordance with records management and Information Assurance requirements as applicable.

Figure 1. Research Test Management Process for Human Participants.



* Flight Operations Authority approval also required for flight test activities.

HEATHER L. PRINGLE,
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Attachment 1

GLOSSARY OF REFERENCES AND SUPPORTING INFORMATION

References

Title 32 Code of Federal Regulations, Part 219, *Protection of Human Subjects,* current edition

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

DoD Directive 5000.2, *Operation of the Defense Acquisition System,* 12 May 2003

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

AFI 91-202, *US Air Force Mishap Prevention* Program, 24 Jun 2015, AFMC Supplement 17 May 2017, AFRL Supplement 14 March 2019

AFI 99-103, *Capabilities-Based Test and Evaluation,* 18 Nov 2019

AFMAN 33-363, *Management of Records,* 01 March 2008

AFRLI 40-402, *Using Human Subjects in Research,* 13 April 2016

AFRLI 61-103, *AFRL Research Test Management,* 28 October 2015

Prescribed Forms

None

Adopted Forms

AF Form 847, *Recommendation for Change of Publication*

Abbreviations and Acronyms

AFRL IRB (711 HPW/IR)— Air Force Research Laboratory Institutional Review Board

CFR—Code of Federal Regulation

ORM—Operational Risk Management

PM—Program Manager

RDT&E—Research, Development, Test and Evaluation

TEA—Test Execution Authority

TD—Technology Directorate

Terms

Generalizable Knowledge—New information that has relevance beyond the population or program from which it was collected, or information that is added to the scientific literature.

Human Subject Research—A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge, when there is intervention or interaction with a human as the subject of the research. This does not include activities, including program evaluation, customer satisfaction surveys, user surveys, outcome reviews, and other methods, designed solely to assess the performance of DoD programs where the results of the evaluation are only for the use of Government officials responsible for the operation or oversight of the program being evaluated and are not intended for generalized use beyond such program. (For further discussion, guidance, and related terminology see DoDI 3216.02_AFI 40-402, *Protection of Human Subjects in and Adherence to Ethical Standards in Air Force Supported Research*, and AFRLI 40-402, *Protection of Human Subjects in Research).*

Human Subject—A living individual about whom an investigator conducting research obtains:

(1)—Data through intervention or interaction with the individual, or

(2)—Identifiable Private Information (PII).

(For further discussion, guidance, and related terminology see—DoDI 3216.02_AFI 40-402, *Protection of Human Subjects in and Adherence to Ethical Standards in Air Force Supported Research*, and AFRLI 40-402, *Protection of Human Subjects in Research*).

Human Participant—A living individual who is not the subject of the test activity but who affects the test activity through intervention or interaction. The focus of data collected is not about the individual, but rather is about the object or design being tested.

Test Activity—For the purposes of this instruction, is an evaluation, demonstration, development, experiment, or other effort, which may or may not encompass Human Subject Research.

Test Activity Involving Human Participants—Any test activity that includes the use of humans through intervention or interaction and is NOT Human Subject Research. This typically applies in cases where the human being is not the focus of the test activity. For example, to use a human to evaluate the sound quality and physical comfort of a stereo headset, the human would not be the focus/subject of the test.

Attachment 2

WORKSHEET FOR ASSESSING APPLICABILITY OF HUMAN SUBJECTS RESEARCH REGULATION EXAMPLE

Figure A2.1. Worksheet for Assessing Applicability of Human Subjects Research Regulation Example.

WORKSHEET FOR ASSESSING APPLICABILITY OF HUMAN SUBJECTS RESEARCH REGULATIONS (Attachment 2) Example only

This worksheet is to be accomplished digitally through the AFRL Enterprise Business System (EBS). It is provided here as an example and for those instances where EBS is not functioning and for awareness of what is implemented in EBS.

Step 1: Does this project meet the definition of research, per the regulatory definition found in 32 CFR 219:

Research is defined as: A **systematic** investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research whether or not they are conducted or supported under a program that is considered research for other purposes.

_____A. *The activity is a **systematic** investigation.* A **systematic investigation:** involves a predetermined, organized plan for collecting information. Utilizes research methodology and includes a plan for data analysis.

_____B. *Designed to develop or contribute to **generalizable** knowledge:* Includes activities that may not produce generalizable knowledge in of themselves, but are intended to lead to it (for example: preliminary or pilot studies as the basis for further research). Is designed to yield answers to a clearly stated research question, test a specific hypothesis, or develop a theory. **Generalizable knowledge:** The intent to expand understanding of a condition or population, or add to the body of knowledge regarding a field of study. Generalizable knowledge means new information that has relevance beyond the population or program from which it was collected, or information that is added to the scientific literature.

Note: This does not include activities, including program evaluation, customer satisfaction surveys, user surveys, outcome reviews, and other methods, designed solely to assess the performance of DoD programs where the results of the evaluation are only for the use of Government officials responsible for the operation or oversight of the program being evaluated and are not intended for generalized use beyond such program.

If YES to BOTH 1 and 2 above, the project meets the definition of **research.** Continue below to step 2 to determine if it qualifies as HUMAN SUBJECTS RESEARCH:

Note: If a project has multiple components and at least one of those components is considered human subjects research, the entire project is classified as human subjects research unless the components are separable.

Step 2. Does this project include HUMAN SUBJECTS per the regulatory definition found in 32 CFR 219?

__C. This project includes obtaining information **or** bio specimens through *intervention* or *interaction* with the individual and uses, studies or analyzes the information or bio specimens. **Intervention** includes both physical procedures by which information or bio specimens are gathered (such as 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.

__D. This activity will obtain, use, study analyze or generate identifiable private information or identifiable bio specimens. **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. **Identifiable bio specimen is a bio specimen** for which the identity of the subject is or may readily be ascertained by the investigator or associated with the bio specimen.

If YES to C **OR** D, the research involves human subjects. To sum, if YES to A **AND** B **AND** either C **OR** D, the activity is subject to human subjects research regulations per this worksheet. Indicate below:

___Yes _____No _____Indeterminate/Not Sure

Step 3: Does this project involve FDA-regulated investigational device activity, per 21 USC 321 and 812:

_____ Is a "medical device" (e.g., a device that effects the function or structure of the human) the focus of the activity, and a human is being used to assess the safety or effectiveness of the device?

If the activity is either FDA or human subjects research regulated activity (or Indeterminate/Not Sure) per this worksheet, the project manager must ensure the activity is reviewed by the Air Force Research Laboratory Institutional Review Board (711th HPW/IR) IAW all applicable Federal, DoD and local regulations. The AFRL IR administrative staff can be reached at 937-904-8100 or afrl.ir.protocolmanagement.@us.af.mil/. Templates: https://usaf.dps.mil/teams/10213.

Attachment 3

HUMAN SUBJECT RESEARCH WORKSHEET/ITEMS TO INCLUDE IN A TEST PLAN INVOLVING HUMAN PARTICIPANT IN TEST ACTIVITIES

A3.1. NOTE: This outline contains many suggested topics to trigger your thoughts to cover all necessary topics. However, some may not be applicable to your specific program. Tailor the outline to fit your program.

A3.2. If living humans are required: To participate in the test activity outside the role of the Program Manager, investigator, or investigative staff, of a test, the following items must be included in this section:

A3.2.1. Total number of participants

A3.2.2. Inclusion/exclusion criteria: screening, qualifications (skills) for participants and/or special tests required

A3.2.3. Identify participant's background (active/retired military, reserve, civilian)

A3.2.4. Age range of participants

A3.2.5. Risk factors and mitigation of risk efforts

A3.3. Describe in detail: The role the human participants will play in the test. For example, what a participant will experience while taking part in the test. Summarize all pertinent information needed to follow the complete course of a test session and perform an adequate evaluation of the test design with regard to human participation. This section should lay out in detail how the participant will interact with test device or equipment, whether directly or indirectly.

A3.4. If any special skills are required of participants or investigative staff: The ability of participants or investigative staff to accomplish those skills must be evaluated prior to test participation (examples include swimming, sky diving, serving as a pilot, driving, licensure, etc.).

A3.5. Describe all possible hazards, risks and discomforts to: Participants to include both physical and psychological risks. For each identifiable risk, provide information on its incidence, the availability and effectiveness of treatment, and possible long-term or permanent effects. Include information on efforts taken to minimize any risks and maximize safety. Provide a comprehensive summary of all medical support requirements of the test program to include precautionary or preventative medicine measures required, if applicable.

A3.6. Specify any support required: Or any special safety precautions that need to be in place to ensure the protection of the human participant. If medical observers are needed, clearly state their qualifications, roles, and responsibilities.