AFWERX · SPACEWERX

# Regulatory Compliance Initial Safety Assessment

For DAF FY26 Releases

**Purpose & Instructions:** All SBIR/STTR Phase II applicants must submit information for a comprehensive initial safety assessment to ensure all proposed research aligns with federal safety regulations and standards. This assessment confirms that funded efforts comply with all relevant safety guidelines.

Completing these questions carefully and thoroughly will minimize the risk of administrative delays or disruptions during the contract award process in the event your proposal is selected for funding. Your collaboration helps us foster a culture of safety and ensure that all projects proceed with appropriate precautions in place.

**Proposal #:** _____

**Deliverables:** Provide information on the types of deliverables being proposed.

1. What are the deliverables for this activity? (Check all that apply and explain all deliverables.)
   - ☐ Hardware (COTS)
     _____
   - ☐ Hardware (Developed under contract)
     _____
   - ☐ Hardware (Other)
     _____
   - ☐ Software (COTS)
     _____
   - ☐ Software (Developed)
     _____
   - ☐ Data Only
     _____
   - ☐ No deliverables
   - ☐ Unknown at this time

2. Will any deliverables or government equipment receive, process, display, store, or transmit government data?
   - ☐ Yes (Explain)
   - ☐ No
   - ☐ Unknown at this time

3. If the answer to Question 2 is Yes or Unknown, will the data be classified?
   - ☐ Yes
   - ☐ No
   - ☐ Unknown at this time

**Equipment:** Identify if any government owned equipment will be used.

**4.** Will any government owned equipment be used for this activity?

- ☐ Yes (Explain)
- ☐ No, exclusively contractor owned equipment will be used
- ☐ Unknown at this time

**Performer:** Identify the types of parties that will be part of this effort.

**5.** Who will perform this activity? (Check all that apply)

- ☐ Government (military or civilian)
- ☐ Contractor (list contractor if known; specify if support or external contractor)

  _____
- ☐ Other _____
- ☐ Unknown at this time

**Performer Location:** Provide information about where the research activities will occur
*Note: Do not include non-research aspect, such as meeting or reviews.*

**6.** Where will this activity occur? (Check all that apply)

- ☐ Government owned facilities (Specify base and/or building name if applicable)

  _____
- ☐ Contractor owned facilities (Specify contractor and facility)

  _____
- ☐ Military owned ranges (Specify military owned range)

  _____
- ☐ Other National Airspace (Specify)

  _____
- ☐ OCONUS (Specify)

  _____
- ☐ Other (Explain)

  _____
- ☐ Unknown at this time

**7.** Will this activity occur indoor or outdoor? (Check that that apply)

- ☐ Indoor (lab)
- ☐ Outdoor (field)
- ☐ Outdoor in an outdoor lab (field)
- ☐ Unknown at this time

**8.** Will this activity regularly utilize an existing AFRL lab?

- ☐ Yes (Specify lab(s)) _____
- ☐ No
- ☐ Unknown at this time

**Test Lead:** Identify if AFRL will be the lead testing organization.

**9.** Will AFRL be the lead testing organization for all efforts executed as part of this activity?

- ☐ Yes
- ☐ No (Specify lead) _____
- ☐ Unknown at this time

**Related Work:** Identify if this proposal is part of a larger effort.

**10.** Is this an extension of a previous program or work unit? (Please indicate if this is a follow-on to a Phase I SBIR/STTR contract.)

- ☐ Yes (Specify) _____
- ☐ No

**11.** What are the future plans for this activity? (Check all that apply)

- ☐ Follow-on activity within AFRL (Briefly describe scope)
  _____
- ☐ Transition outside of AFRL to specific customer (Specify customer)
  _____
- ☐ Transition outside of AFRL, customer not confirmed
- ☐ No follow-on or transition planned
- ☐ Unknown at this time

**Standard Operating Procedures (SOPs):** Identify if this activity will fall under a SOP that has been approved by the local AFRL Det/SE office. If yes, provide more information.

**12.** Will this activity fall under approved Standard Operating Procedures (SOP(s))?

- ☐ Yes (Specify SOP(s)) _____
- ☐ No
- ☐ Unknown at this time

**Space Activity:** Identify if this activity involves space activities.
*Note: Space Systems include all the devices and organizations forming the space network. These consist of launch vehicles, launch ranges, launch and range support equipment and systems, spacecraft, mission, and user terminals (See AFI 91-202).*

**13.** Will this activity involve designing or operating a flight-ready space system or spacecraft payload intended to operate in actual space missions?

- ☐ Yes
- ☐ No
- ☐ Unknown at this time

**14.** Will any part of this activity include launching hardware or software into orbit or occur in space during this contract?

- ☐ Yes (Specify which milestone(s)) _____
- ☐ No
- ☐ Unknown at this time

**15.** If the answer to Question 12 is Yes, will the government have control over the hardware, software, or system during spaceflight? (Mark N/A if above question is No)

- ☐ Yes
- ☐ No
- ☐ Unknown at this time
- ☐ N/A

**Flight-Related Activity:** Identify if this activity involves flight-related activities.
**If you answer yes to any of these questions, you will also need to complete the Flight Activity Information Worksheet** (attached).
*Note: Flight is any set of related events where a vehicle moves through the air making use of the physics of controlled or maneuvering aerial transport. Includes balloon flight but does not include activities where the flight path is solely ballistic in nature. (See AFRLI 61-103 Vol 1).*

**16.** Will this activity include any flight? If yes, please complete the Flight Activity Information Worksheet (attached).

- ☐ Yes (Specify which milestone(s)) _____
- ☐ No

**17.** Will this activity NOT include flight but WILL include taxiing an aircraft (manned or unmanned)? If yes, please complete the Flight Activity Information Worksheet (attached).

- ☐ Yes (Specify which milestone(s)) _____
- ☐ No

**18.** Will this activity include flight inside an enclosed facility? (Outdoor netted facility, indoor flight testing, etc.) If yes, please complete the Flight Activity Information Worksheet (attached).

- ☐ Yes (Specify which milestone(s)) _____
- ☐ No

**IMPORTANT!**
If you answered "Yes" to any questions in the Flight-Related Activity section (questions 16, 17, or 18), you must complete the FLIGHT ACTIVITY INFORMATION WORKSHEET that follows.

**Hazardous Materials:** Identify if this activity involves hazardous materials as defined below:

***Directed Energy:*** *technologies that relate to the production of a beam or field of concentrated acoustic or electromagnetic energy or atomic or subatomic particles. (See AFI 91-401)*
***Ammunition:*** *any munition designed to be thrust from a gun barrel by expanding gasses resulting from burning propellant (See DSER 6055.09)*
***Munition:*** *a complete device charged with explosives, propellants, pyrotechnics, initiating composition, or chemical, biological, radiological, or nuclear material for use in operations including demolitions. (See AFPD 21-2)*
***Energetic Material:*** *ammunition, munition fliers, demolition material, solid rocket motors, liquid propellants, cartridges, pyrotechnics, mines, bombs, grenades, warheads of all types, explosives elements of ejection and aircrew egress systems, air-launched missiles, and those explosive components of missile systems and space*
*systems, and assembled kits and devices containing explosive material. (See DSER 6055.09)*
***Electromagnetic Radiation:*** *radiation made up of oscillating electric and magnetic fields and propagated with the speed of light. Includes gamma radiation, X-rays, ultraviolet, visible, and infrared radiation, and radar and radio waves. (See DSER 6055.09)*
***Munitions Systems:*** *include any release, control, suspension, and dispersal devices. This includes all suspension systems (including racks, launchers, and rails), dispensers, or packaging devices used to contain or disperse non-nuclear explosive devices, or used as the direct launching platform.*

**19.** Will this activity use directed energy devices? This includes weaponized or non-weaponized lasers, microwaves, particle beam devices, or acoustic weapons.

- ☐ Yes, in free space (Specify type, power levels, and which milestone(s))
  _____
- ☐ Yes, in a laboratory environment (Specify type, power levels, and which milestone(s))
  _____
- ☐ No
- ☐ Unknown at this time

**20.** Will this activity involve explosives of any size or type? This includes, but is not limited to, ammunitions, propellants, munitions, or energetic materials.

- ☐ Yes (Specify which milestone(s)) _____
- ☐ No
- ☐ Unknown at this time

**21.** Will this activity involve electromagnetic radiation? This includes, but is not limited to, radio waves, gamma rays, and X-rays.

- ☐ Yes (Specify which milestone(s)) _____
- ☐ No
- ☐ Unknown at this time

**Hazardous Materials, cont'd:** Answer the questions below about hazardous materials.

**22.** Will this activity involve a munitions system (e.g. delivery platforms, launchers, guidance systems, or support equipment)?

- ☐ Yes (Specify which milestone(s)) _____
- ☐ No
- ☐ Unknown at this time

**23.** Will this activity use any other kind of hazardous material not already specified in questions 19-22?

- ☐ Yes (Specify hazardous materials and which milestone(s))

  _____
- ☐ No
- ☐ Unknown at this time

**Human Subject Research (HSR):** Identify if this activity involves human subject research. These particularly relate to efforts in which researchers obtain data or identifiable private information about living individuals through intervention or interaction with the individual. This can include the use of human organs, tissue, body fluids, as well as graphic, written, or recorded information. *(See 32 CFR 219, DAFPD 40-4, and DoDI 3216.02_AFI 40-402)*

**24.** Will the project involve interaction or intervention with humans? If yes, please complete the HSR Information Worksheet (attached).

- ☐ Yes (Specify which milestone(s)) _____
- ☐ No

**25.** Will this activity involve infectious agents and toxins, human-derived materials, or recombinant DNA? If yes, please complete the HSR Information Worksheet (attached).

- ☐ Yes (Specify which milestone(s)) _____
- ☐ No

**IMPORTANT!**
If you answered "Yes" to any questions in the Human Subject Research section (questions 24 or 25), you must complete the HSR INFORMATION WORKSHEET that follows.

**Animal Testing:** Identify if this activity involves animal testing. "Animal" is defined as any living or dead vertebrate animal, including birds, cold-blooded animals, rats of the genus Rattus, and mice of the genus Mus. With respect to avians and other egg laying vertebrate species, their offspring are considered animals only after hatching. With respect to fish and amphibians, their larval offspring are considered animals. For the purposes of this definition, "dead" is defined as animals killed for the direct purpose of conducting RDT&E or training. However, it does not include dead animals or parts of dead animals purchased at grocery stores or slaughterhouses. *(See DoDI 3216.01)*

**26.** Will this activity involve vertebrate animals?

- ☐ Yes (Specify which milestone(s)) _____
- ☐ No

**Radio Frequency:** Identify if this activity involves radio frequency use.

**27.** Will this activity include radio frequency (RF) use? This includes, but is not limited to, communications, transmitting information, radios, radars, and datalinks.

- ☐ Yes (Specify which milestone(s)) _____
- ☐ No
- ☐ Unknown at this time

**IMPORTANT!**
If you answered "Yes" to any questions in the Flight Related Activity section (questions 16, 17, or 18), you must complete the FLIGHT ACTIVITY INFORMATION WORKSHEET that follows.
If you answered "Yes" to any questions in the Human Subject Research section (questions 24 or 25), you must complete the HSR INFORMATION WORKSHEET that follows.

**Flight Activity Information Worksheet**

**Purpose & Instructions:** The Air Force Research Laboratory (AFRL) serves as the Lead Test Organization (LTO) for all flight activities associated with Department of the Air Force SBIR/STTR contracts. As LTO, AFRL is responsible for the oversight and management of all aspects of flight testing to ensure all activities are conducted safely and in strict compliance with Department of the Air Force (DAF) regulatory and operational standards.

The information provided in the worksheet is critical for evaluating airworthiness, assessing potential safety risks, and ensuring compliance with safety protocols for experimental and operational flight activities. Thorough responses will enable AFRL to conduct a rigorous safety evaluation and implement necessary risk mitigations. Providing comprehensive detail will minimize the risk of administrative delays or disruptions during the contract award process in the event your proposal is selected for funding. Your collaboration helps us foster a culture of safety and ensure that all projects proceed with appropriate precautions in place.

## General Details:

**FA1.** Provide a general description of the proposed flight test program (4000 characters max):

**FA2.** Concisely describe your general and specific test objectives (4000 characters max):

**FA3.** Describe the number and duration of flight test events (4000 characters max):

**FA4.** Anticipated First Flight Test Date (MM/DD/YYYY): _____

**Aircraft:** Answer questions FA5 though FA19 for each aircraft involved in the activity.

**FA5.** Aircraft Involved:

☐ To the best of my ability, I have listed all the aircraft that will be involved in this activity.

**FA6.** What type of aircraft will be utilized (Check all that apply)

- ☐ Fixed Wing
- ☐ Rotary Wing
- ☐ Unmanned Aerial System (UAS)
- ☐ Other

**FA7.** If UAS is selected in question FA6 above, estimate DoW UAS Group: (Check all that apply)

- ☐ Group 1 (Small, 0-20 lbs, <1,200 ft AGL, <100 kts)
- ☐ Group 2 (Medium, 21-55 lbs, <3,500 ft AGL, <250 kts)
- ☐ Group 3 (Large, <1320 lbs, <18,000 ft MSL, <250 kts)
- ☐ Group 4 (Larger, >1320 lbs, <18,000 ft MSL, Any kts)
- ☐ Group 5 (Largest, >1320 lbs, >18,000 ft MSL, Any kts)

**FA8.** Provide the make/model and basic specifications such as size, weight, maximum altitude, and max air speed:

**FA9.** Identify if the air vehicle is a new design, modification of an existing design, or no modifications will be needed to execute your flight test:

**FA10.** Will the aircraft be leased?

☐ Yes (Specify who will be leasing the aircraft at the time of the flight activity. Provide specific contractor or government organization.)

☐ No (Specify who will own the aircraft at the time of the flight activity. Provide specific contractor or government organization.)

**FA11.** Does the government have an interest in owning the aircraft at a later time?

☐ Yes (Explain)

☐ No

**FA12.** Does the government have an interest in owning any of the spectrum dependent equipment which is part of this system?

☐ Yes (Explain)

☐ No

**FA13.** Will there be any government furnished equipment (GFE) on the aircraft?

☐ Yes (Specify proposed GFE and its value)

☐ No

**FA14.** Will there be any spectrum dependent government furnished equipment (GFE) on the aircraft?

☐ Yes (Explain)

☐ No

**FA15.** What is the cost of the aircraft, including any modifications or systems under test? (Include ground equipment and equipment flown on other aircraft)

**FA16.** Will the aircraft carry any personnel in addition to the required flight crew?

☐ Yes (Describe the role of all personnel onboard the air vehicle)

☐ No

**FA17.** Who will operate the aircraft?

☐ Contractor Employee
☐ Subcontractor Employee
☐ Government Employee
☐ Other (Explain)

**FA18.** Is the aircraft insured for the proposed flight activity? (To include loss or damage of the vehicle, liability, injury to persons on board aircraft – please provide the declarations page of insurance policy or estimated future coverage as an attachment)

☐ Yes
☐ No
☐ If Yes, I have attached the declarations page of insurance policy or estimated future coverage as an attachment with my proposal.

**FA19.** If this activity includes UAS use, does the UAS contain any components made in the People's Republic of China (PRC)?

☐ Yes (Explain)

☐ No

## Location

**FA20.** Where will the aircraft be operated? (Select all that apply)

☐ Enclosed space (building, netted enclosure, etc.)

☐ Open Air

**FA21.** Where will the proposed flight operations take place (specify city, state, test range, facility, type of airspace, etc)? (Specify all proposed flight operations locations.)

## Other Implications

**FA22.** Are the proposed flight activities exclusively for testing purposes?

☐ Yes

☐ No (Specify other, e.g. training, exercise, etc.)

**FA23.** Will the aircraft be ferried as part of the contract before, during or after the test program?

☐ Yes (Explain)

☐ No

## Potential Risk

**FA24.** Will flight activities involve testing of aircraft subsystems?

☐ Yes (Specify which systems)

☐ No

**FA25.** Will the aircraft be used to carry (either integrated into the aircraft or simply carried by the aircraft) the item being tested?

☐ Yes (Explain)

☐ No

**FA26.** Will the flight activity be used to test development or reliability of aircraft components?

☐ Yes (Explain)

☐ No

**FA27.** Will the flight activity be conducted to determine or demonstrate critical operating characteristics of an aircraft?

☐ Yes (Explain)

☐ No

**FA28.** Will the flight activity involve high angle of attack tests?

☐ Yes (Explain)

☐ No

**FA29.** Will the flight activity involve flutter tests?

☐ Yes (Explain)

☐ No

**FA30.** Will the flight activity involve load tests?

☐ Yes (Explain)

☐ No

**FA31.** Will the flight activity involve critical stores separation tests?

☐ Yes (Explain)

☐ No

**FA32.** Will the flight activity include flights to determine or expand flight or propulsion system envelopes?

☐ Yes (Explain)

☐ No

**FA33.** Will the flight activity include flights to determine performance, flight characteristics, and/or handling qualities?

☐ Yes (Explain)

☐ No

**FA34.** Will the flight activity include flights of an aircraft whose flight characteristics may have been altered by configuration changes?

☐ Yes (Explain)

☐ No

**FA35.** Will the flight activity include initial flights of aircraft which have undergone “major modification”?

☐ Yes (Explain)

☐ No

**FA36.** Will the flight activity include component development flights where failure of the test component would make the flight hazardous in nature and/or involve greater than normal risk?

☐ Yes (Explain)

☐ No

## Execution

**FA37.** How will the planned flights be executed?

- ☐ Civil Aircraft Operations (CAO) (the activity will occur under FAA rules)
- ☐ Public Aircraft Operations (PAO) (an aircraft operation is "public" when the aircraft is owned by the government, or is operated by the government or operates outside of the purview of the FAA airworthiness certificate)
- ☐ Certificate of Authorization (COA) (the activity will be performed by UAS under FAA approval) (Explain)

**FA38.** Will the aircraft be used for any military type activities (i.e. not just testing), such as carrying a weapon or launching a missile?

- ☐ Yes (Explain)
- ☐ No

## Proper Use Memo

**FA39.** Does the airborne system include any sensors that could be used to observe personnel on the ground? This may include any open-air data collection to include imagery, full motion video, electro optical/infrared (EQ/IR), Light Detection and Ranging (LIDAR), Synthetic Aperture Radar (SAR), Wide Area Motion Imagery. NOTE: If you answer "Yes" to FA37, a Proper Use Memorandum may be needed to ensure compliance with laws regarding domestic intelligence collection.

- ☐ Yes (Describe type of sensor)
- ☐ No

## Human Subject Research Information Worksheet

**Purpose & Instructions:** All SBIR/STTR Phase II applicants must submit information for a comprehensive human subject research (HSR) assessment to ensure all proposed activities align with federal regulations and Department of the Air Force (DAF) ethical standards. This assessment confirms that funded efforts protect the rights and welfare of all research participants.

The information provided in this worksheet is critical for determining whether proposed activities meet the requirements for Institutional Review Board (IRB) approval and Human Research Protection Official (HRPO) concurrence. Thorough responses will enable a rigorous ethical evaluation and help identify necessary compliance milestones. Completing these questions carefully and thoroughly will minimize the risk of administrative delays or disruptions during the contract award process. Your collaboration helps us foster a culture of safety and ensures that all projects proceed with the appropriate safeguards in place.

**Does this project meet the definition of research, per regulatory definition found in 32 CFR 219?**

**HSR 1.** Is the activity a systematic investigation? A systematic investigation involves a predetermined, organized plan for collecting information. Utilizes research methodology, and has a plan for data analysis.

- ☐ Yes
- ☐ No

**HSR 2.** Is the activity 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.

- ☐ Yes
- ☐ No

## Does this project include HUMAN SUBJECTS per regulatory definition found in 32 CFR 219?

**HSR 3.** Does the project include 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.

- ☐ Yes
- ☐ No

**HSR 4.** Will this activity 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.

- ☐ Yes
- ☐ No

## Does this project involve FDA-regulated investigational device activity per 21 USC 321 and 812?

**HSR 5.** Is a "medical device" (e.g., a device that affects 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?

- ☐ Yes
- ☐ No

## General Details:

**HSR 6.** Describe the purpose of the proposed activity, clearly identifying your company's role in the activity:

**HSR 7.** Provide a thorough description of the procedure:

**HSR 8.** Describe the type of information that will be collected:

**HSR 9.** Explain how the information will be collected or obtained (i.e. identify source of data):