Regulatory Considerations: Project Hurdles

Presented by: Ms. Candice Gebhardt, Ms. Rachel Braun and Ms. Tina Opoku

Overview

- Flight Testing
- Section 848 of 2020 NDAA
- Human Research
- Animal Testing
- Cybersecurity
- Industrial Security
- Other Project Hurdles
- Q & A

Flight Activity

Flight Activity

What is flight or flight-related activity?

- Any set of related events where a vehicle moves through the air making use of the physics of controlled or maneuvering aerial transport
  - Includes manned or unmanned aircraft and small UAS
  - Includes balloon flight, attritable aircraft, and may include indoor flight
  - Includes taxi, aircraft ground test, cockpit evaluations, and other similar activities

Why does it matter?

- AFRL provides basic guidance for the conduct of flight test activities that:
  - Utilize resources owned, possessed, leased, expended, or operated by AFRL (personnel, aircraft, equipment, facilities, **funding**, etc.)
- Needed to ensure a suitable level of technical rigor and to provide assurance of safe and efficient execution of flight or flight-related activities

Flight Activity Process

Planning, Review and Approval

- Process supported by your government program manager, AFRL DO and others
  - Kickoff Meeting
  - Flight Test Planning Meeting (FTPM) – pathway to test approval
  - Technical Review (TRB) – technically sufficient?
  - Safety Review (SRB) – is it safe?
  - Airworthiness, cyber, security, spectrum, etc.
  - Test Approval and Flight Approval

All process steps are tailored to the specifics of your situation.

Don’t worry - we are here to help you through this!

Flight Activity Contract Clauses

Ground and Flight Risk Clause (DFARS 252.228-7001)

- Used when government has *an interest* in the aircraft (not Contractor-Owned, Contractor-Operated, Civil Aircraft Operations (COCO/CAO) - this exemption is new)
  - Government Owned or Government Operated
  - Government furnished equipment or
- Requires contractor to follow DCMA 8210.1 procedures

Mishap Reporting and Investigation Involving Aircraft, Missiles, and Space Launch Vehicles (DFARS 252.228-7005)

Liability and Insurance (252.247-7007)

Other contract text requiring contractor support to:

- Test planning and design reviews
- AFRL Technical Review Boards and Safety Review Boards
- Air Force mishap investigations
- Identify lessons learned
- Flight test vehicle airworthiness

Section 848 of the 2020 NDAA

Section 848 2020 NDAA

The statute

- "Prohibition on Agency Operation or Procurement.--The Secretary of Defense may not *operate* or enter into or renew a contract for the *procurement* of a covered unmanned aircraft system…"
  - Affects DoD and DoD contractors
  - Applies UAS and UAS critical components made in the People's Republic of China such as:
    - Flight controller, radio, data transmission device, camera, gimbal, ground control system, operating software, network connectivity, data storage
  - Does not apply to components that include passive electronics (electronic parts that do not process, store, or retain data) or structural materials

Section 848 2020 NDAA Implementation

DoD Policy

- Previous (2018) Deputy Secretary of Defense memorandum is cancelled
- New policy memo dated 8 September, 2021 affects DoD and DoD contractors
- What are the choices?
  - Blue List are systems considered non-COTS or Program of Record
    - Pre-approved
  - Compliant UAS requires ***exception to policy (ETP)*** from service component
  - Made in China requires ***waiver*** of law by Secretary of Defense
    - Exceptions for counter-UAS surrogate testing
- Many factors impact how the law and the new policy are implemented
  - Several exceptions exist
  - An ETP is considerably easier to get than a waiver
  - Contact AFRL/DO for assistance

Human Subject Research

Human Subjects Research (HSR) - Definition

“Human subject” means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information (32 CFR 219.102(f)). For example, this could include the use of human organs, tissue, and body fluids from individually identifiable living human subjects as well as graphic, written, or recorded information derived from individually identifiable living human subjects.

“Research” means a systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of 32 CFR Part 219, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities (32 CFR 219.102(d)).

DFARS 252.235-7004 Protection of Human Subjects

DAF/DoD Protection of Human Subjects

- **The DoD and DAF add further protections for human subjects in research**
- In addition to an Institutional Review Board (IRB) approval or determination, HSR must undergo review and concurrence by a Human Research Protections Officer (HRPO)
    - Proposals are reviewed to determine if they *may* involve HSR
        - Reviews are conducted by “Gatekeepers”
        - Reviews are *not* IRB determinations

[DoD Instruction 3216.02: Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research]

HRPO Process

- If the Gatekeeper finds that a proposal *may* involve HSR, DFARS clause 252.235-7004 must be included in the contract (DoDI 3216.02, 3.6 b. (1))
- Gatekeeper considers two aspects of the proposal
  - Is this research as defined by the DFARS clause?
  - Are human subjects involved?

Research means a systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information (32 CFR 219.102(f))

AFWERX
AFVENTURES

HRPO Process

- The DFARS clause requires the performer to obtain an external IRB review after award
  - IRB may approve through expedited or convened board procedures
  - IRB may exempt study (8 possible types of exemptions, but *still HSR*)
  - IRB may determine that the activity is *not* HSR
- Following external IRB review, all materials are forwarded for HRPO concurrence
- Once HRPO concurrence is obtained, the research can be funded (i.e, may begin)
  - Performer may be able to receive funds to conduct work not involving HSR prior to HRPO review

Key Message: In effect, an IRB submission may be needed to know whether an IRB submission is needed. This is *not* an arbitrary AFWERX decision but is a result of federal laws/regulations and DoD policies.

Animal Testing

Animal Testing

- Animal testing process is much like HSR
- DAF funded animal research contracts must also contain the DFARS clause 252.235-7002
- Key differences between human research and animal testing:
    - Institutional Animal Care and Use Committee (IACUC) instead of IRB
    - Second level review done (also before funding) by USAF Animal Research Oversight & Compliance office of the AF Medical Readiness Agency (AFMRA)
    - Animal use involving non-human primates, dogs, cats, marine mammals, and/or live-tissue training requires an on-site compliance assessment

DODI 3216.01 Use of Animals in DoD Conducted and Supported Research and Training


ESTABLISHED
MMXX
AFWERX
AFVENTURES
Cybersecurity

Cybersecurity - What's Your Why

Nearly half of all cyber attacks target small businesses (single incident costs a small business business an avg of ~$100k).

When working with the Government, assume that your company is an even bigger target for a malicious cyber attack than the average small business.

Ensure you're continuously putting safeguards in place to keep your employees, your IP, and DoD information safe from malicious attacks and unintentional data spillage.

Baseline Cybersecurity Needs

You are responsible for protecting your data and Government data from malicious attacks and unintentional data spillage.

- Get familiar with FAR/DFARs* cyber requirements
- Report any cyber incidents and facilitate incident investigations
- Self-assessments in SPRS (Supplier Performance Risk System) and documentation via a System Security Plan (SSP)
    - DoD's single, authorized application to retrieve supplier performance information
    - Requires get-well plans for unimplemented controls via Plan of Action w/Milestones (POAM)
- Implement NIST SP 800-171 standards
    - This includes (~110) security measures to protect "covered data" - CUI, ITAR, PII, health data, etc.

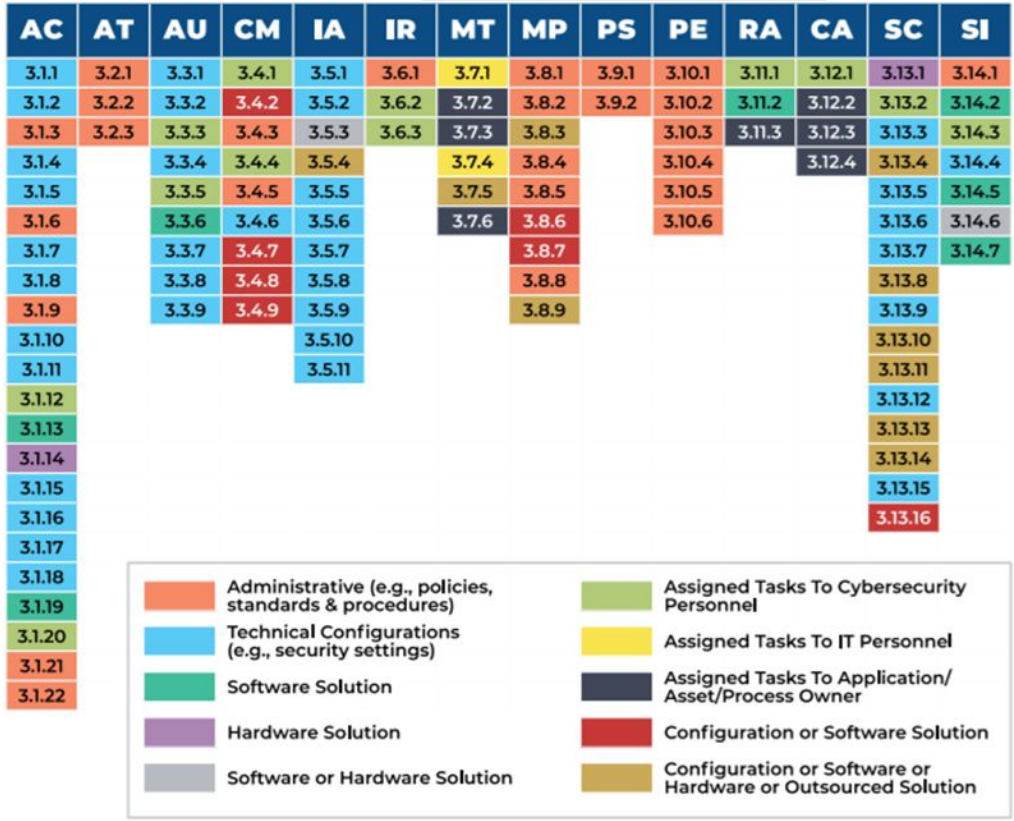
*FAR 52.204-21 - Basic Safeguarding of Covered Contractor Information Systems
DFARS 252.204-7012 - Safeguarding Covered Defense Info & Cyber Incident Reporting
DFARS 252.204-7020 - NIST SP 800-171 DoD Assessment Requirements

Control Examples from NIST SP 800-171 (8 of 110)

EASIER

HARDER

- Ensure all system users receive cyber risk training
- Limit unsuccessful login attempts
- Periodically scan for vulnerabilities & assess risks
- Control and monitor user-installed software
- Separate user functionality from system mgmt
- Establish baseline configurations
- Implement multi-factor authentication
- Employ FIPS-validated cryptography



AFWERX
AFVENTURES

Paths to Software Authorization

All software or IT systems connecting to DAF information systems must first receive an authorization!

Authorizing Official (program/system specific)

- Approval to Use (ATU) - AFRL approval to deploy solution to Govt approved cloud
- Interim Authorization to Test (IATT) - Faster, temporary approval to test prototype solutions
- Authorization to Operate (ATO) - Utilizes the Risk Management Framework (RMF) to grant ongoing approval with conditions and agreements based on continual re-assessments and cyber hardening by the company and Gov program office

Software Factories (e.g. Platform One, Cloud One)

- Enables faster/cheaper software deployments within DevSecOps environments

FEDRAMP

- USG-wide approach to certifying software

Keep in Mind

- Not all software/IT systems require ATOs
- Interim authorizations are quicker/easier to obtain than an ATO (may work better for prototyping phases)
- Some cases *will* require an ATO
  - Customer Orgs are responsible for working these requirements with the applicable Authorizing Official (AO)
  - Note: Each AO and software factory has a slightly different process or focus
  - When working toward an ATO is appropriate, milestone language sometimes leads to PoP extension requests due to Gov't delays
- When writing a proposal
  - Avoid: "obtain Government ATO" or "complete accreditation"
  - Better: "investigate ATO process & document way forward" or "complete package documentation for ATO approval"

Resources to Rely On

For help getting started or for support with specific questions:

Who is the Authorizing Official?
Every DoD information/weapon system is assigned an AO. This senior-level official is responsible for any risks from ATOs they grant.

Customer/Weapon System Cyber Shops & Authorizing Officials

DAF Chief Information Officer 'Blue Cyber' website

- Bootcamps, weekly AMAs, topic specific videos, and 1 on 1s
  https://www.safcn.af.mil/CISO/Small-Business-Cybersecurity-Information/

DoD Office of Small Business Programs' Project Spectrum

- Helps SBCs determine current level of security based on NIST 800-171, CMMC reqs

ODNI NCSC (Director of Nat'l Intelligence, National Counterintelligence + Security Center)

- Cyber Training

Cybersecurity mentors

- State PTACs (Procurement Technical Assistance Center)
- SCORE Foundation for small businesses

Industrial Security

Industrial Security

Base Access

- Visitor's Pass or Sponsorship needed - TPOC can coordinate with local visitor's center
- If frequent or recurring installation access is required, a CAC request may be appropriate

Network Access

- A CAC is required for most DoD system access
- An Authorization to Operate (ATO) may also be required if you plan to connect any new IT to DAF systems, or ingest controlled data

Classified Access (FCL, personnel clearance, data processing & storage)

- A DD-254 is required for all classified access. Your customer must draft this with their local security office, then the company can submit via contract mod request. The Contracting Officer is the final signature.

CAC Request Process

1. TASS Form 1 processed by TA
2. If not already in DISS, a Form 306 and Proof of Citizenship is required to initiate T1 investigation
3. Upon favorable investigation, TA loads information into DISS & TASS
4. Contractor will receive email to register in TASS
5. Contractor will receive instructions to receive CAC at local DEERS office (via appointment)

DD Form 254

- This form is used to add the Gov't requirement for classified access to your contract.
- It specifies the types of accesses required, cognizant security office, and specific security guidance
- Once a DD-254 is on contract, the cognizant security office is then authorized/responsible for initiating the clearance and access processes.

Other Project Hurdles

Other Project Hurdles

Government Furnished Equipment (GFE)

Follow organization's guidance that is providing the equipment, send final safety certification to AFVentures Phase II team

Environmental & Safety (hazardous materials)

DODI 4715.06 Environmental Compliance. The Military Base and/or State/Local govt may have additional requirements

Munitions/Explosives

Work closely with DAF customer, following local ordinance guidance, and comply with US State Department's International Traffic in Arms Regulations (ITAR)

May require contractor to meet certain facility security, safety and inspection requirements

May require Non-Nuclear Munitions Safety Board (NNMSB) followed by safety review board by Org handling the munitions/explosives

Other requirements as defined by policy

Questions?

Please type your questions in the Q&A.