

## **What to Submit for HRPO Review**

### **For studies determined to be “not research” or “research that does not involve human subjects”:**

- Protocol, IRB submission form, or other document that will guide the conduct of the research
- Any/all other documents submitted to and reviewed by the office that made the “not research” or “not human subjects” determination
- Documentation of the non-DoD institution’s review and determination

### **For exempt human subjects research studies:**

- Research protocol or IRB submission form
- Any/all other documents submitted to and reviewed by the office that made the exempt determination
- Documentation of investigators’ training in the protection of human subjects
  - May be training certificates or documentation of institutional policy requirements for training
- Documentation of the non-DoD institution’s review and determination
  - Must include the category/categories of exempt research determined to be applicable

### **For all non-exempt human subjects research studies:**

- Research protocol
- IRB submission form (if separate from protocol)
- Recruitment materials (e.g., flyers, posters, emails, Facebook ads, etc.)
- Informed consent document or justification for waiver of consent/documentation of consent
- Study instruments (e.g., surveys, interview scripts, case report forms)
- Product information (e.g., investigator’s brochure, package insert for drug being tested)
- Any/all other documents submitted to, reviewed, and approved by the IRB
- Letter(s) of support from supporting Air Force institution(s)
  - If AF members will be recruited, include documentation that their commander supports their participation in the research.
- Documentation of investigators’ training in the protection of human subjects
  - May be training certificates or documentation of institutional policy requirements for training
- Documentation of FWA coverage for all engaged investigators
  - Individual Investigator Agreements, and Institutional Agreements for IRB Review should be provided as appropriate when collaborating/subcontracting aspects of the research
- Documentation of IRB review and approval
  - Notification provided by the IRB to the investigators
  - Documentation must include:
    - IRB’s risk determination (minimal risk/greater than minimal risk)
    - Type of IRB review (expedited/full board and, if expedited, what category the study was found to meet)
    - Time period until next review/study expiration
    - Any additional determinations relevant to the study (e.g., FDA, waiver of consent, regulatory category for research involving children)

Send final, IRB-approved versions of all documents, and any other required documents to [usaf.pentagon.af-sg.mbx.afmsa-sge-c@mail.mil](mailto:usaf.pentagon.af-sg.mbx.afmsa-sge-c@mail.mil) . Documents should NOT be combined into a single file.