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| **General Submission Information** |
| **Instruction:** * Principal Investigators (PI) must submitonly final, Institutional Review Board (IRB) or Ethics Committee (EC) approved versions of all documents to the Department of the Air Force Program Managers/Officers (DAF PM/PO) or Technical Point of Contact (TPOC) and copy AFRL.IR.HRPO@us.af.mil.
* DAF PM/PO’s must review and assist PI’s in submitting submissions to AFRL.IR.HRPO@us.af.mil.
	+ For SBIR/STTR submissions resulting from AFWERX/SpaceWERX awards, the PI may submit direct to HRPO.
* Do not combine documents into a single file (i.e. no combined pdf).
* Unclassified zipped and large files (up to 8.0 GB) must be submitted through [DoD SAFE](https://safe.apps.mil/) to AFRL.IR.HRPO@us.af.mil
* Distribution A designation on this checklist applies only when it is blank.
 |
| **Important:*** HRPO review will not begin until a complete submission package is received.
* The DAF PM/PO and the non-DoD PI will be contacted for any additional required information.
* After review is complete, a HRPO concurrence letter will be issued to the DAF PM/PO/TPOC, Award Officer and the PI will be copied.
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| **DoD Contact Information** |
| **Instruction:** This section should be completed by the DAF PM/PO/TPOC for this project.  |
| **DAF PM/PO/TPOC Name:** |  | **Official E-mail:** |  |
| **Directorate / Organization:** |  | **DAF PM/PO/TPOC** **Phone #:** | Primary: |
|  |  |  | Secondary: |
| **Grant or Contract Manager:** |
| **Name:** |  | **Official E-mail:** |  |
| **Grant / Contract / Proposal Number:** |  | **Grant or Contract Manager Phone #:** | Primary: |
|  |  |  | Secondary: |
| **Grant / Award Title:** (if applicable) |  |
| **Name of Awardee:** |  |
| **Please consult with the Grant/Contract Officer or DAF PM/PO/TPOC to respond to the following:** |
| **Does the award include augmenting the non-DoD study personnel with DoD personnel?** | [ ]  Yes | [ ]  No |
| If **Yes**, please explain in the row below or indicate the location where this provision of government furnished personnel can be found in the award documentation: |
|  |
| **DAF PM/PO Confirmations**  |
| **Note:** This section is **not applicable** for TPOC’s for AFWERX/SpaceWERX awards.  |
| **As the DAF PM/PO, I understand and agree to the following:** |
|[ ]  I am responsible for ensuring the final HRPO determination is received by the Award Officer (e.g., DAF Contracting Officer/Grants Manager) noted above. |
|[ ]  I have included the Statement of Work/Proposal, with this HRPO submission. |
|[ ]  Before Human Subjects Research (HSR) conducted outside the USA proceeds, I will assist the key investigator identify an appropriate contact at the Command (U.S. Africa, U.S. European, U.S. Indo-Pacific or U.S. Southern) where HSR will be conducted or supported in their area of responsibility so that the command may be provided with written notification of this activity, per DoDI 3216.02 Section 1.2.g.  |
| **Choose one:** |
|[ ]  I have included a fully executed copy of the Grant/Contract/Award (and sub-awards, as applicable) that includes the required information listed in the “Note” row below, with this HRPO submission. |
| **OR** |
|[ ]  I attest that the required information, as listed in the “Note” row below, has been included in the executed award (and sub-awards, as applicable).  |
| **Note:** The award should include: (1) language that notes an obligation to comply with HSR requirements per DoDI 3216.02; (2) the full text of the DFARS clause for Contracts and similar language for other agreements that identifies the non-DoD Institutions’ responsibilities and (3) restricts the performance of prospective DoD supported HSR until the HRPO’s concurrence is provided.  |

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| **Non-DoD Contact Information** |
| **Instruction**: The remainder of this document should be completed by the PI or Designee.  |
| **Individual at the Investigator’s Institution Completing this Checklist:** |
| **Name:** |  | **Official E-mail:** |  |
| **Relationship to PI:** |  | **Phone #:** | Primary:  |
|  |  |  | Secondary:  |
| **PI & Institution Information:** |
| **PI Name:** |  | **PI Institution:** |  |
| **Institutional Position:** |  |
| **Official E-mail:** |  | **PI Phone #:** | Primary:  |
|  |  |  | Secondary:  |
| **IRB/EC Name:** |  |
| **PI Confirmations** |
|  **The PI confirms that he/she understands and agrees to the following:** |
|[ ]  I have completed or certify each completed element of the checklist and that it is true and accurate. |
|[ ]  I understand that DoD supported human research cannot begin until successful completion of HRPO review (i.e., issuance and receipt of HRPO concurrence for non-exempt human research, exempt human research, or activities that are not research/not research with human subjects). |

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| **Section 1.0: General Study Information** |
| **Protocol Title:** |  |
| **1.1 Provide the following information regarding your funding:**  |
| Amount | Type (e.g, Science & Technology) | Source (the supporting DoD Component, or AFRL Directorate) |
|  |  |  |
| **1.2 What type of study is being submitted?** |
| **Research Type** | **Parts to Complete** |
|[ ]  Not Research/Not Research with Human Subjects | **Part A** |  |  |
|[ ]  Exempt\* |  | **Part B** |  |
|[ ]  Non-Exempt  |  | **Part B** | **Part C** |
|  | [ ]  Minimal Risk | **OR** | [ ]  Greater than Minimal Risk |  |  |  |
| \* Informed consents/information sheets used in Exempt projects should contain the following statements:* “The U.S. Department of Defense is providing support for the research.”
* “The U.S. Department of Defense personnel responsible for the protection of human subjects will have access to research records.”
 |
| **1.3 In which country will this research be conducted?** | [ ]  USA | [ ]  EU | [ ]  Other: |  |
| If only **US**, proceed to the next section.  |
| **1.4 If in the EU, was this study reviewed in compliance with the General Data Protection Regulation (GDPR)?** | [ ]  Yes | [ ]  No |
|  If **No**, please explain: |  |
| **1.5 If this study is being conducted outside of the USA, the IRB/EC approval letter must address the following elements:** |
|[ ]  Confirm the HSR is compliant with applicable laws and requirements of each foreign country where the HSR will be conducted; |
| ☐ | The IRB/EC considered the (1) local research context, (2) including cultural sensitivities of foreign research subjects before approving participation of foreign research subjects in the foreign countries;  |
|[ ]  The IRB/EC must provide documentation of the source of information about the foreign research context (via letters from consultants and/or in IRB minutes). |
| **1.6 If this study is being conducted outside the USA, prior to HSR proceeding the Key Investigator must provide written notification to the Command (U.S. Africa, U.S. European, U.S. Indo-Pacific or U.S. Southern) where HSR will be conducted or supported in their area of responsibility, per DoDI 3216.02 Section 1.2.g.**  |
| [ ]  Written documentation the Command was notified is included with my submission. |
| **Note:** Please work with your DAF PM/PO/TPOC to facilitate this written notification.  |

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| **Part A** |
| **Section 2.0: Submission Requirements** |
| **Instruction:** * Submit final versions of all documents the IRB/EC reviewed in making their determination. At a minimum, submitted documentation should include the full description and purpose of the activity, how the results will be used and to whom the results will be distributed. Provide any information that justifies/supports the determination that the activity is not research or is research that does not involve human subjects.
* Submit the Protocol and IRB/EC submission form (if applicable).
* Submit documentation of IRB/EC’s or Institutional determination (including justification for the determination) if the activity is not research or research not with human subjects.
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| **Note:** Additional supporting documentation may be requested. |

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| **Part B** |
| **Section 3.0: Protocol & Study Population** |
| **Instruction:** Submit a copy of the IRB/EC approved research protocol (study plan) and/or IRB/EC application. |
| **Note:** Certainstudies (e.g., exemption determinations, studies using data only) may not include all the elements noted below and should therefore be marked as No. |
| **3.1 Does the protocol address the following elements?**  |
| **Yes** | **No** | **Protocol Elements** | **Additional Information** |
|[ ] [ ]  Scientific rationale/merit.  | For non-exempt research approved by the IRB/EC (expedited & full board reviews) documentation that the IRB/EC considered the scientific merit of the study is required.  |
|[ ] [ ]  Study purpose and hypothesis. |
|[ ] [ ]  Study design. | Is there a description of research procedures and any procedures that are considered experimental? |
|[ ] [ ]  Subject selection. | Inclusion/exclusion criteria; Number of subjects targeted; and any certain countries/populations targeted. |
|[ ] [ ]  Recruitment and informed consent plan. | Is there a description where, when, by whom, and how these tasks will be performed? |
|  |  | **Submit** all IRB/EC approved recruitment materials (e.g., call scripts, e-mail text, flyers, and social media ads). |
|[ ] [ ]  Description of research tools and how they will be used. | Equipment, screening tools, surveys, questionnaires, data collection sheets, screen shots of on-line forms, videos. |
|  |  | **Submit** all IRB/EC approved tools and/or investigator brochures for any equipment, devices, or drugs to be used. |
|[ ] [ ]  Reasonably foreseeable risks and their expected frequency/severity.  | Certain risks may require a risk mitigation plan to be included in the protocol. |
|[ ] [ ]  Probable benefits for participant and society. |
|  |  | **Note:** Monetary compensation is NOT a benefit. |
|[ ] [ ]  Safety monitoring. |
|[ ] [ ]  Data management and confidentiality. | Does the protocol describe how data will be maintained (identifiable or de-identified, coded etc.); where research study records will be kept (locked files in a secure office, password protected and/or encrypted electronic records); Who will have access to the data and for what purposes; and when/how will data be destroyed? |
|[ ] [ ]  Data sharing plan/agreement(s) and plans for future use (if applicable). | If research data will be shared the protocol must describe who, what, where, how and when if there is any plan to share research data with others and/or used for future research. |
|  |  | If **Yes**, is this plan:  | [ ]  Part of the Protocol | [ ]  A Freestanding Document |
| **3.2 Will DoD-affiliated personnel be targeted for recruitment?**  |
| [ ]  No | If **No**, proceed to the next section. |
| [ ]  Yes | If **Yes,** consult with the HRPO office and respond to the following:  |
| **Note:** Additionalrequirements may be applicable. The protocol should describe the following elements: if compensation is being provided, command permission for off-duty employment; prohibition against superiors influencing participation of subordinates; prohibitions against superior’s presence at recruitment or during the consent process; and the Ombudsperson selected for group recruitment sessions.  |
| **3.2.1 Will you recruit DoD-Affiliated personnel from:**  |
| [ ]  DAF | If **DAF**, and the supporting DAF institution does not have a human research protection program, it must establish a limited human research protection program (or “Limited HRPP”). Please contact the HRPO office for more information on how to proceed.  |
| [ ]  Other DoD Components | If **Other DoD Components**, the DoD-affiliated personnel’s commander and/or the commander of the facility must provide a letter of support. Please contact the HRPO office for more information on how to proceed.  |
| **3.3 If the study is non-exempt *and* greater than minimal risk, will US DoD-affiliated personnel be recruited in a group setting?** | [ ]  Yes | [ ]  No | [ ]  N/A |
| If **Yes**, the IRB/EC must appoint an ombudsperson who (1) must not have a conflict of interest and not be part of the study team; (2) must be present during HSR recruitment and ensure consent is voluntary; and (3) is available to address US DoD-affiliated personnel’s concerns about participation.  |
| **Please identify the Ombudsperson**: |  |

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| **Section 4.0: IRB/EC Review and Institutional Requirements** |
| **Instruction:** Submit a copy of the IRB/EC Approval Letter along with all IRB/EC approved documents including any submission forms used by the IRB/EC during their review. * Approval letter must include:
	+ Exempt Determinations: Category AND sub-category for all research, including written justification and documentation of the determination. Including written documentation (narrative) of the limited IRB review for any applicable exempt research determination.
	+ Expedited Review: the letter must include the federal register category that was applied.
	+ Documentation of approval period (time until next review or study expiration).
 |
| **4.1 Will this study be conducted at additional institutions?** | [ ]  Yes | [ ]  No |
| If **Yes**, the protocol must include a full description of additional institution(s) involvement and whether other investigators will be engaged. |
| **4.2 Have any other IRB/ECs reviewed this study?** | [ ]  Yes | [ ]  No |
| If **Yes**, additional IRB Review documentation may be required.  |
| **4.3 For non-exempt research, the reviewing IRB/EC must consider the scientific merit of this project per DoDI 3216.02 section 3.6.b(6)(a)1.**  |
|[ ]  I **confirm** supporting documentation that the IRB considered during their review is attached with my submission. |
|[ ]  Not Applicable |
| **4.4. For exempt research, certain categories require a limited IRB review. Was this review conducted?** | [ ]  Yes | [ ]  No | [ ]  N/A |
| If **No**, please explain: |  |
| **4.5 Have all necessary ancillary reviews pertaining to this project been conducted (such as, biosafety, radiological etc…)** | [ ]  Yes | [ ]  No | [ ]  N/A |
| If **No**, please explain: |  |
| **4.6 Does this project involve Artificial Intelligence (AI) enabled tools or capabilities?** | [ ]  Yes | [ ]  No |
| If **Yes**, did the IRB document that the [DoD Ethical Principles for AI](https://www.defense.gov/News/Releases/Release/Article/2091996/dod-adopts-ethical-principles-for-artificial-intelligence/) were considered and appropriately provided for in the protocol ? | [ ]  Yes | [ ]  No |
| If **No**, please explain: |  |
| **4.7 Was additional scientific merit review required to consider whether the DoD ethical principles for AI were appropriately implemented?** | [ ]  Yes | [ ]  No |
|[ ]  If **Yes**, I confirm it was documented in writing and documentation is attached to this submission. |

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| **Section 5.0: Study Personnel** |
| **5.1 Complete the embedded Investigator Spreadsheet.** * Identify members of the study team, their role, institutional affiliation, and training information.
* Submit the PI’s CV.
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| **Note**: Human subjects protections training must be current within 3 years of submission to HRPO. Additional documentation may be required including, but not limited to: CV’s, IRB review agreements or individual investigator agreements.  |

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| **Section 6.0: Additional Requirements** |
| **6.1 Does this project include Large Scale Genomic Data (LSGD) from DoD-Affiliated Personnel?** | [ ]  Yes | [ ]  No |
| If **Yes**, DoD supported research involving LSGD collected on DoD-affiliated personnel, is subject to additional requirements per DoDI 3216.02. Please contact the HRPO office in advance if your research activity involves LSGD. Refer to the Extramural Submission Instruction for additional information. |

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|  **Part C** |
| **Section 7.0: Non-Exempt IRB/EC and Institutional Requirements** |
| **7.1 Does this study involve a product that may be regulated by the Food and Drug Administration (FDA), this includes devices and drugs?** | [ ]  Yes | [ ]  No |
| If **Yes,** documentation that the IRB/EC considered FDA regulatory requirement, the risk of the investigational product and documentation of compliance with applicable regulations is required. Submission of manufacturer information and FDA Approval or Clearance information for each product may be required. |
| **7.2 Will this study involve Protected Health Information?** | [ ]  Yes | [ ]  No |
| If **Yes**, IRB/EC approved HIPAA authorization or documentation that a waiver of HIPAA authorization was approved is required. |

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| **Section 8.0: Special Study Population(s)** |
| **8.1 Will the research enroll any individuals from the following special populations?**  |
| [ ]  N/A | [ ]  Pregnant Women, Fetuses and Neonates (Subpart B) |
| [ ]  Prisoners (Subpart C)  | [ ]  Children (Subpart D) |
| If **applicable**, submit documentation of the IRB/EC’s deliberation regarding the relevant Subparts of 45 CFR 46. |

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| **Section 9.0: Informed Consent / Information Sheet** |
| **Instruction**: Submit final IRB/EC approved Informed Consent (IC) (may also be referred to as an Information Sheet) documents or IRB/EC approval documentation for waiver(s) of documentation of IC, as applicable. |
| **IMPORTANT**: Consent to provide medical care is different than consent to participate in research.  |
| **9.1 Will this study enroll individuals with diminished capacity, such as children or those that require a legally authorized representative (LAR)?** | [ ]  Yes | [ ]  No |
| If **Yes**, submit applicable assent(s), permission form(s) or the plan for gaining consent from the LAR.  |
| **Note**: The PI is responsible to ensure the person providing consent to participate in a research study has been legally delegated the authority.  |
| **9.2 Does this study involve either of the following:** |
| [ ]  Waiver of IC\* | [ ]  Waiver of Documentation of IC; complete 9.3 | [ ]  N/A; complete 9.3 |
| \* 10 USC 980 Stipulates that funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless IC is obtained in advance. Please contact the HRPO to discuss, if applicable. |
| **Note**: Any request for waiver of consent will require additional documentation needed for DAF review and approval. |
| **9.3 Please confirm that each of the following elements are included in your IC.**  |
| **Yes** | **No** | **IC Element** |
|[ ] [ ]  A statement that the study involves research. |
|[ ] [ ]  Explanation of the research purpose. |
|[ ] [ ]  Expected duration of subject’s research participation. |
|[ ] [ ]  Description of research procedures, including a description of any experimental procedures. |
|[ ] [ ]  Description of reasonably foreseeable risks or discomforts to subjects (consistent with the protocol). |
|[ ] [ ]  Description of any reasonably expected benefits to subjects or others (consistent with the protocol).  |
|  |  | **Note**: Monetary compensation for participation is NOT considered a benefit. |
|[ ] [ ]  Alternatives for subjects (e.g., not to participate), if applicable. |
|[ ] [ ]  Description of confidentiality procedures for research records. |
|[ ]  **Required** | The following required statements:* “The U.S. Department of Defense is providing support for the research.”
* “The U.S. Department of Defense personnel responsible for the protection of human subjects will have access to research records.”
 |
|  |  | **Note**: Comparable alternate language may also be acceptable. Please contact the HRPO office via the address provided on page 1 of this checklist for approval of alternate language before submission for HRPO review. |
|[ ] [ ]  For research of greater than minimal risk, an explanation as to whether any compensation or medical treatments are available for any injury and, if so, what they consist of, or where more information can be obtained. |
|[ ] [ ]  An explanation of whom to contact with questions about the research (e.g., the PI), subject rights (e.g., the IRB/EC), and whom to contact regarding research-related injury (e.g., the PI). |
|[ ] [ ]  The following statements: * Participation is voluntary.
* Refusal to participate will not involve penalty or loss of benefits to which subjects are otherwise entitled.
* Subjects can discontinue participation at any time will not involve penalty or loss of benefits to which subjects are otherwise entitled.
 |
|[ ] [ ]  If identifiers are being collected include one of the following statements:* “Identifiers might be removed from the data and non-identifiable data could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.”
* “Your data collected as part of the research, from which identifiers are removed will not be used or distributed for future research studies.”
 |
| If **No** to any of the above elements,please explain: |  |