|  |  |
| --- | --- |
| **General Submission Requirements** | |
| 711 HPW/IR serves as the designated office of the AFRL Human Research Protections Official (HRPO), appointed by the AFRL/CC, who services as AFRL’s Institutional Official (IO) for human research protections. | |
| For more information about requirements of DoD-Supported research please reference the embedded information sheet. |  |
| * The purpose of this document is to ensure all submission requirements are met. * Human Research Protection Official (HRPO) review will not begin until the non-DoD submission is complete. * All submission requests and related correspondence must be sent directly to the AFRL HRPO org inbox: [AFRL.IR.HRPO@us.af.mil](mailto:AFRL.IR.HRPO@us.af.mil) * Submit all documentation in Microsoft Word or PDF. Do not combine PDF documents into a single file. * Label each document to facilitate quick identification of contents. This should include, if possible, the version date and/or version number. * Only provide final, Institutional Review Board (IRB) / Ethics Committee (EC) approved documents (no drafts or documents with tracked changes will be accepted unless requested by the HRPO office). * Submit the complete package to the DAF Program Manager/Program Officer (PM/PO) and copy the HRPO org box noted above.   + For SBIR/STTR submissions resulting from AFWERX/SpaceWERX awards, the PI may submit direct to HRPO.   + E-mail is the preferred route of submission.   + IMPORTANT: **Zip Files** attached to an email and the associated email will both be deleted by AF IT security and will never reach the HRPO.   + Contact the HRPO office for a [DoD SAFE](https://safe.apps.mil/) submission upload link for secure transmission of very large files (up to 8 GB). Submissions with greater than 25 documents will require additional DoD Safe links. DoD Safe also supports zip files. * Submit all responses to the DAF PM/PO and copy the HRPO org box noted above. * Items listed below are the minimum necessary required for HRPO review. Additional items may be required at the discretion of the HRPO. * If the activity has an existing HRPO review from another DoD Component (Army or Navy), submit a copy of the existing HRPO determination to [AFRL.IR.HRPO@us.af.mil](mailto:AFRL.IR.HRPO@us.af.mil) before completing this form. Duplicate HRPO reviews may not be required. * After review is complete, a HRPO concurrence letter will be issued to the DAF PM/PO, Award Officer (AO) and the Principal Investigator (PI) will be copied. | |
| **Note:** Contact the HRPO via the AFRL HRPO org box with any questions, as needed. If an AFRL ID number has been assigned, include the AFRL ID in the subject line of the email correspondence | |

|  |
| --- |
| **Initial Review** |
| **Submission Requirements:**   * The PI of activities that require Initial Department of the Air Force (DAF) HRPO review should:   + Complete applicable sections and submit the Extramural Research Initial Submission Checklist.     - Complete Part A for not research or research not involving human subjects.     - Complete Part B for exempt research.     - Complete Part B & C for non-exempt research. * Embedded within Part B is an Investigator Spreadsheet where study staff details are required.   + Engaged study personnel must document:     - The individuals name, study title and role;     - The individual’s institutional affiliation; and     - Document human subject protection training (typically conducted via CITI program), current within 3 years or documentation of alternate institutional policy regarding Human Subjects Research (HSR) training requirements.   + Each institution engaged in non-exempt HSR must be covered by a federal wide assurance (FWA). Submit the FWA and IRB Registration number associated with the FWA with the expiration dates for each on this spreadsheet. The IRB registration number is **NOT** the protocol number assigned by the local IRB/EC   + Engaged personnel not covered or linked to an institution that has an assurance may execute an Individual Investigator Agreement (IIA) with the assured institution. An authorized institutional official from the assured institution must sign this IIA. |
| **Required Documentation:**   * Award (contact the PM/PO for assistance as needed) * Submit a copy of the executed award agreement (Contract/OTA/Cooperative Agreement or Grant) between the DAF and the prime awardee and any sub awards executed between the prime and any sub-awardee that documents the requirements related to human subject research and HRPO review requirements (i.e. DFARS clause); or * For projects that are not related to an AFWERX/SpaceWERX award, have the DAF PM/PO or AO provide written documentation or an attestation (on the checklist) that the required information per DoDI 3216.02\_DAFI 40-402 regulatory requirement was included in the executed award. * **Note**: The award should include the full text of the DFARS clause for Contracts and similar language for other agreements. In addition to identifying the non-DoD Institutions’ responsibilities, the award must restrict the performance of prospective DoD supported HSR until the HRPO’s concurrence is provided. * Statement of Work (SOW) * Submit to HRPO a copy of the SOW or proposal that describes the component approved research activity for both the Prime and any sub-awards. * IRB/EC Application/Submission * IRB Approved Study Protocol (plan) * IRB Approved Informed Consent Document(s) * IRB Approval Letter should include the following best practice common elements: * Correct Protocol Title, * IRB/EC determination and justification of determination as applicable (not research or not research involving human subjects, expedited review category and subcategories, exempt determination category and subcategories), if a limited IRB was conducted the IRB must provide an analysis as to how the requirements of the privacy and confidentiality provisions have been met, * Approval Date & Expiration, * Written documentation from the IRB/EC that Scientific Merit was considered during review of all non-exempt research. * Risk Determination (Minimal or Greater than Minimal Risk), * Language granting any waiver request, * List of documents reviewed by the IRB/EC (if applicable), * Documentation of applicable regulatory requirements that were used to review the study (such as FDA and HIPAA regulations,) * Signature or Name and title of IRB/EC approving official (if applicable), * Whether the IRB documented that the DoD Ethical Principals for Artificial Intelligence were considered and appropriately provided for in the protocol. * All additional IRB/EC approved documents such as: surveys, questionnaires, and recruitment material. |

|  |
| --- |
| **Modifications / Amendments** |
| **Instruction:** Investigators are responsible for obtaining prior approval from the IRB/EC for any modifications or proposed changes of the previously approved research, to include, but not limited to, modifications to the informed consent process and supporting documents. Changes may not be instituted without IRB review and approval except when necessary to eliminate apparent immediate hazards to subjects.  The HRPO must review and approve substantive changes to protocols and documentation prior to implementation to include but not limited to:   * Any modifications that could potentially increase risk to subjects, * Change in Principal Investigator, * Change or addition of an institution, * Elimination or alteration of the consent process, * Change in the IRB of Record, * Change to the study population that has regulatory implications (e.g. adding children, adding active-duty population, etc.), and * Significant change in study design (i.e. would prompt additional scientific review).   HRPO will send an acknowledgement memo to the PM/PO once all requirements are verified as complete. |
| **Required Documentation:**   1. All IRB approved modified materials, 2. Track change versions (so HRPO can readily identify changes), 3. IRB modification request form, and 4. Corresponding IRB approval letter that specifies the new approval date. |

|  |
| --- |
| **Continuing Review / Re-Approval** |
| **Regulatory Basis:**   * Continuing Review (CR) is a periodic review of a research protocol by the IRB. The review must be substantive and meaningful. Per DoDI 3216.02\_DAFI 40-402, the non-DoD institution must promptly notify HRPO “The Results of the IRB’s/EC’s continuing review, if required” |
| **Instruction:** PM’s/PO’s and PI’s will be notified when the protocols they oversee are approaching expiration. Notices are sent 4 weeks prior to the non-DoD IRB protocol expiration date to remind the PM/PO to submit the required documentation within 2 weeks of the IRB expiration date. Each CR package must be complete with all documents clearly identified. The subject line of the email must reference the DAF assigned identifier (one protocol per email)**.**  At the time of CR the supporting DAF institution (PM/PO/AO) is responsible to verify the award remains active and convey this to HRPO.  Once review is complete the HRPO will either issue comments requesting additional information or issue an acknowledgement of the CR. |
| **Required Documentation:**   * Results of the IRB/EC’s continuing review (if required) to include the following documentation: * IRB/EC re-approval letter that documents the new IRB approval period * Progress report or renewal submission form/request * IRB/EC Approved Protocol/Consent, data collection forms or recruitment materials that includes the current approval period |
| **IMPORTANT:** Approval periods expire at 11:59 pm on the expiration date issued by the IRB/EC. If the study expires, the PI must cease all research activities, including all enrollment and data analysis. Any continuation of research activity is a violation of DoD and Federal regulations. PI’s who want to continue research activities must submit a renewal request to their IRB. Research activities may not resume until a new IRB approval has been issued. |

|  |
| --- |
| **Study Closure** |
| **Regulatory Basis:**   * Per DoDI 3216.02\_DAFI 40-402: The non-DoD institution must promptly notify HRPO “of a DoD-supported study’s closure”. |
| **IRB/EC Closure** |
| **Required Documents:**  Within 2 weeks of closure, HRPO must receive the following from the DAF PM/PO:   1. A copy of the IRB closure form submitted by the PI to the IRB stating the intent to close the research study, and 2. The IRB’s acknowledgement that the study was closed. |
| **Note:** A protocol is considered “closed” when all of the following are met:   1. The research is permanently closed to enrollment, 2. All subjects have completed all research related interventions and interactions including those related to long term follow-up, and 3. No additional identifiable private information about the subjects is being obtained (or being used in study analysis). |
| **End of DoD Support** |
| **Required Documentation:**   * Within 2 weeks of support end, the DAF PM/PO must confirm the date DoD support ended with the AO and submit written documentation to the HRPO. |
| **Note:** Investigators may wish to continue the research project at their institution after DoD support ends under non-DoD funding / support. If the project becomes supported by the US Department of Defense again at some point in the future, it will require re-submission for HRPO review. |

|  |
| --- |
| **General Guidance** |
| **Extramural Research** |
| * Extramural research is research that is supported by the Department of Defense / Department of the Air Force but conducted by a non-DoD institution and reviewed and approved by a non DoD IRB/EC. Support may include, but is not limited to, funding (grants, contracts, or cooperative agreements), use of DoD facilities or equipment, program management and award management performed by DoD personnel, access to or information about DoD personnel for recruitment, including identifiable data or specimens. * If DoD-affiliated personnel (military or civilian) are engaged, the study is subject to a DoD IRB review. |
| **Assurances and Addendums** |
| * An Assurance is required by any institution (civilian or military) performing HSR supported by any U.S. Federal department/agency that has adopted the Common Rule. A [Federal Wide Assurance (FWA)](https://ohrp.cit.nih.gov/efile/FwaStart.aspx) is acquired through the U.S. Department of Health and Human Services Office for Human Research Protections (OHRP). * An Individual Investigator Agreement (IIA) is a specific assurance used to cover one person. The agreement can be limited to a specific study or set of studies and is used for researchers who do not have a specific institutional affiliation (example: an independent contractor). |
| **Human Subject Protection Training** |
| * Human Subject Protections (HSP) training is required for any individual engaged in the research project. Engaged means that the individual will have direct interaction with subjects or their identifiable data. HSP training must be completed within three years to be considered valid and must remain current while the individual is engaged in the research. A popular service used to take human subject protections training is the CITI Program or HRPO will accept documentation of the institution’s policy regarding HRP training. |
| **Research Records/Audits** |
| Records maintained by non-DoD institutions that document compliance or noncompliance in accordance with DoDI 3216.02 must be accessible for inspection and copying by authorized representatives of the DoD. Representatives of the Department of the Air Force (DAF) Component Office of Human Research Protections (COHRP) have authority and the AFRL HRPO may perform periodic quality assurance audits of the non-DoD institution’s DoD supported human subject research (HSR). Quality assurance visits may consist of the following: a one-on-one interview with the investigator and research staff. Observation of the informed consent process or data collection may also be accomplished at the discretion of the HRPO. The HRPO will notify the supporting AF office (via the PM/PO/Component POC) in writing of the results, any deficiencies, and any corrective actions that may be required. |
| **Recruitment of DoD-Affiliated Personnel or any other DoD support** |
| 1. If the DoD-Supported HSR involves recruitment of DAF-affiliated personnel (active duty, civilian or DoD contractors) will be recruited to participate in HSR or are providing any other support, and the supporting DAF institution does not have a human research protection program (HRPP), it must establish a limited HRPP. The template to facilitate this requirement is available from the AFRL HRPO Office. 2. For other DoD components, If the DoD-supported HSR involves recruitment of DoD-affiliated personnel (active duty, civilian or DoD contractors), the key investigator must receive a command or component letter of support from the DoD-affiliated personnel’s command to conduct the research and before recruiting them as human research subjects. 3. If the DoD supported HSR will be conducted on a DoD facility, the key investigator must also receive approval from the command or DoD Component responsible for the facility. 4. HRPOs must receive written documentation of permission from the DoD institution(s) providing support to HSR activity. The PI is required to obtain a letter of permission from person(s) with authority to provide requested support for the activities described in the protocol, and submit to HRPO for review before conducting the research. 5. The PI must provide to the command or component copies of the IRB approved protocol and informed consent documents for review when requesting approval. |
| **Compensating DoD-Affiliated Personnel in Research Studies** |
| Investigators who plan to compensate DoD-affiliated personnel must comply with regulations and requirements specific to each DoD component (Army, Navy, Air Force and Marine Corps). Each DoD component may have specific requirements regarding compensation paid to DoD affiliated personnel. Investigators must describe their plan for any compensation of DoD affiliated personnel including the military status of potential subjects targeted for enrollment in the IRB application. A summary of current compensation plan for DoD affiliated personnel including military is listed below.  On-duty DoD affiliated personnel, including military members:   * Up to $50 for blood draws if Statute 24 USC 30 is met in conjunction with clinical care or during donation of blood. * Compensation is not allowed for general research participation.   Off-duty DoD affiliated personnel including military members:   * May be compensated for research participation the same way as human subjects who are not Federal personnel (i.e., compensated for participation in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research). However, payment to off-duty Federal personnel for research participation other than blood draws must not be directly from a Federal source (payment from a Federal contractor or other non-Federal source is permissible). * Off-duty employment can be verified many ways, including through an AF form 3902. * Compensation is allowed for general research participation, as approved by the IRB. Payment may not come directly from a federal source. Payment from a federal contractor or non-federal source is permissible. |
| **Note**: It is unlikely that compensation for blood draws is applicable in social behavioral or operational related research. |
| **Large Scale Genomic Data (LSGD)** |
| **Instruction:** Contact the HRPO office if the research involves LSGD of DoD affiliated personnel. DoD-supported research involving LSGD collected on DoD-affiliated personnel, or for which research the DoD provides assistance, is subject to additional requirements per DoDI 3216.02\_DAFI 40-402:   1. Since disclosure of DoD-affiliated personnel’s genomic data may pose a risk to national security; accordingly, such research requires administrative, technical, and physical safeguards commensurate with risk, including the secondary use or sharing of de-identified data or specimens. 2. All research involving LSGD collected from DoD-affiliated personnel will apply a Health and Human Services Certificate of Confidentiality pursuant to Title 42, U.S.C., and Public Law 114-255. 3. Research involving LSGD collected from DoD-affiliated personnel is subject to DoD Component security review to ensure the adequacy of the proposed administrative, technical, and physical safeguards, including the secondary use or sharing of de-identified data or specimens. |

|  |
| --- |
| **Reminders** |
| 1. **This list is not meant to be all inclusive.** Some protocols may be more complex than others and may have additional requirements. You will be advised either by the DAF Program Manager or HRPO if additional documents are needed. |
| 2. **HRPO review will not begin until the package is complete.** Be advised that if items are missing from the initial protocol submission the protocol will be held in a pending status until everything is received before placing the protocol in the queue for processing and subsequent HRPO review. |
| 3. **Each submission stands alone**. Please do not assume that because you have previously submitted documents with a prior study proposal that we will cross reference to those documents (e.g. Addendums, awards). Each submission is viewed as new and therefore must include all required documentation. |
| 4. **Care should be given to ensure all titles match**. The IRB/EC approved protocol title should match the IRB/EC approval documentation (letter) and, the titles on the informed consent documents and recruitment information. For good document control each should include a version number and date, although we understand some IRB’s/EC’s do not include this step. This is also considered good research practice. Please do not use the title of a program/project or grant as the protocol title unless it is the same. **Note**: Some awards often have multiple protocols associated with it. |
| 5. **Ensure a complete list of study personnel with a brief description what each person will be doing is included on the investigator spreadsheet.** HRPO must be able to tell if an individual is engaged or not. Listing only a title (e.g. Faculty, Research assistant) does not explain the tasks each person will be performing, such as consenting or recruitment. |