|  |  |
| --- | --- |
| University of Washington Human Subjects DIvision | **WORKSHEET Department of Defense** |
|  |  |
|  |  |

|  |
| --- |
| **PURPOSE AND APPLICABILITY** |

This Worksheet is used by IRB staff and members as guidance to facilitate the UW IRB review of non-exempt research that involves any component of the federal Department of Defense (DoD). It does not apply to the Limited IRB Review process.

|  |
| --- |
| **INSTRUCTIONS** |

Staff compare this worksheet with the researcher-submitted [**SUPPLEMENT Department of Defense**](https://www.washington.edu/research/forms-and-templates/supplement-department-of-defense/) to help determine whether the requirements listed below apply and if so, whether they have been met. It is not required that this worksheet be completed or retained. Additional information is available in the [**GUIDANCE Department of Defense**](https://www.washington.edu/research/hsd/guidance/specific-agencies/dod/).

|  |
| --- |
| **REQUIREMENTS** |

|  |  |  |
| --- | --- | --- |
| **Requirement**If the requirement does not apply, do not check any boxes. | Yes | No |
| 1. **Is the research classified?**

*If the research is classified, consult with HSD Leadership.* | [ ]  | [ ]  |
| 1. **Has the study been evaluated for scientific merit?**

*Check “Yes” if any of the three mechanisms is checked in the SUPPLEMENT.* | [ ]  | [ ]  |
| **+Guidance**Scientific review is required for all DoD research. The researcher is not required to provide the IRB with a copy of the review. However, the IRB may choose to require it, if it would be helpful in assessing risks, study design, etc. |  |  |
| 1. **Will the study enroll individuals under the age of 18 who are: Service/Reserve/National Guard members in federal duty status; military trainees; or students at a service academy?**
 | [ ]  | [ ]  |
| **+ Guidance** If these individuals are allowed to participate, they are reviewed by the IRB as adults (i.e., do not apply Subpart D of the Common Rule).The IRB must carefully consider the recruiting process and the necessity of including these individuals. |  |  |
| 1. **Does the study plan to enroll prisoners of war (POWs) or military detainees?**

*Information about the study population is in the IRB Protocol, not the Supplement.* | [ ]  | [ ]  |
| **+ Guidance** DoD research **cannot include these individuals** ***unless*** the research involves the use of investigational new drugs or investigational devices when the purpose is for diagnosis or treatment of a medical condition. Such treatments can be offered to POWs and detainees with their informed consent when the use is regulated by the FDA and only when the same product(s) are available to DoD-affiliated personnel, consistent with established medical practices. |  |  |
| 1. **DoD-Affiliated Personnel as Participants**

There are numerous requirements and limitations that must be met for study participants who are DoD-affiliated personnel (Service members and trainees; Reserve Service members; National Guard members; DoD civilian employees and contractors). **If this does not apply to the study, skip to question 6**. |  |  |
| 1. **Did the researcher confirm they will follow the recruiting requirements described in the Supplement?**
 | [ ]  | [ ]  |
| 1. ***If applicable*, did the researcher provide information about the ombudsperson that is required to be present during recruitment?**
 | [ ]  | [ ]  |
| **+ Guidance** An ombudsperson is required for greater than minimal risk research where recruitment will occur in a group setting. The IRB must determine that the individual is appropriate to ensure participation is voluntary and that the information about the study is adequate and true. |  |  |
| 1. **Did the researcher confirm that they will comply with payment requirements?**
 | [ ]  | [ ]  |
| 1. **Did the researcher describe risks to fitness for duty?**

*As appropriate, this information is included in the consent process/form.* | [ ]  | [ ]  |
| **+ Guidance**  *Examples: health, availability to perform job, impact of data breach.* |  |  |
| 1. **Did the researcher describe how (if at all) participation could result in the revocation of clearance, credentials, or other privileged access of duty and how those risks will be managed?**

As appropriate, this information is included in the consent process/form. | [ ]  | [ ]  |
| 1. ***If applicable*, did the researcher confirm that they will follow the requirements associated with collecting genomic data from DoD-affiliated personnel?**
 | [ ]  | [ ]  |
| **+ Guidance** *Large scale genomic data are defined by DoD as data derived from genome-wide associate studies; single nucleotide polymorphisms arrays; genome sequencing; transcriptomic, metagenomic, epigenomic analyses, and gene expression data; etc. Examples include but are not limited to projects that involve generating the whole genome sequence for more than one gene from more than 1,000 individuals or analyzing 100 or more genetic variants in more than 1,000 individuals.* |  |  |
| 1. ***If applicable*, did the researcher confirm that they will include theArmy-required information in the consent form and HIPAA Authorization?**

Check the box if the study involves the Army and the researcher has confirmed in the SUPPLEMENT they will include the required information in the consent and HIPAA forms. | [ ]  | [ ]  |
| 1. ***If applicable*, did the researchers confirm, and does the IRB Protocol reflect, the following consent restrictions for experimental subjects?**
* Consent can only be waived for records procedures, screening activities, and EFIC (EFIC must be approved by DoD in addition to the IRB).
* Consent elements may be waived for minimal risk research so long as the consent process informs subjects that participation is voluntary and describes the research risks.
* LAR consent is only allowed if the research is intended to provide a benefit to the individual subject.
 | [ ]  | [ ]  |
| 1. ***If applicable*, has the researcher obtained research-related injury requirements from the DoD and have those requirements been provided to the IRB and included in the consent form?**
 | [ ]  | [ ]  |
| **+Guidance**If the research is DoD-conducted, and is greater than minimal risk, there are DoD-specific requirements about the treatment of research-related injuries and how they are described in the consent form. The IRB review process cannot be fully completed until those requirements have been incorporated into the consent form and provided to the IRB. UW IRB accepts any requirements, including language, unless those requirements impose obligations on the UW to promise treatment. If such obligations appear to exist, HSD Leadership is consulted. |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 5.2 | 03.02.2023 | 03.02.2023 | Moved content to current TEMPLATE Worksheet; moderate reorganization and wordsmithing throughout |
| 5.1 | 04.28.2022 | 04.28.2022 | Make “experimental subjects” its own question rather than embedding under “DoD personnel” |
| 5.0 | 12.28.2021 | 12/28/2021 | Significant revision and reorganization in response to revised DoD regulations |
| 4.3 | 05.27.2021 | 05/27/2021 | Remove references to paper processes |
| 4.2 | 11.02.2020 | 11/02/2020 | Removed medical monitor requirements |
| Previous versions |  |  | For older versions: HSD Staff - see the SharePoint Document Library; Others - contact hsdinfo@uw.edu. |

**Keywords:** Federal agencies